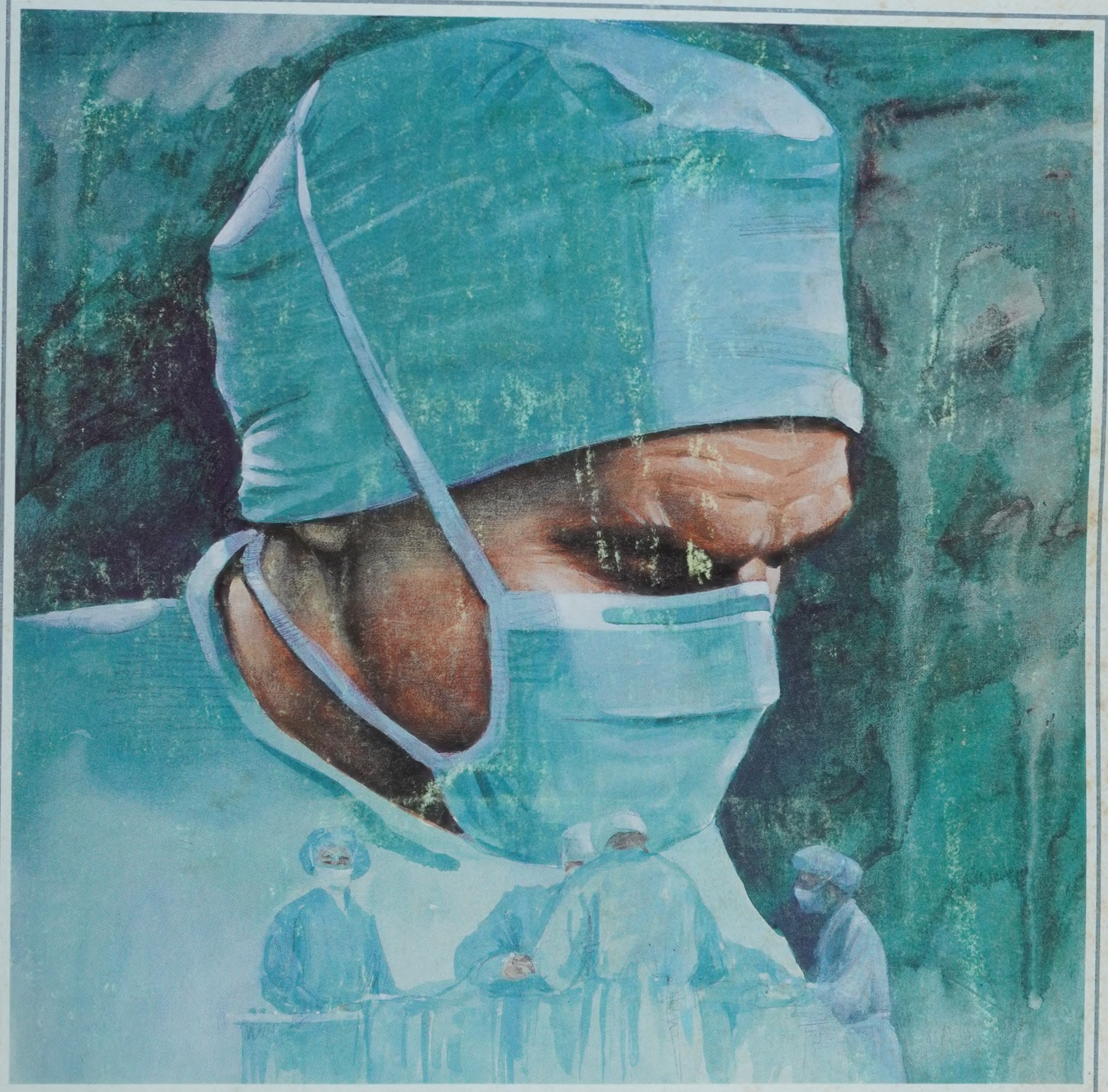
# WOUND CLOSURE MANUAL



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# Wound Closure Manual

## Use and Handling of Sutures, Needles and Mechanical Wound Closure Devices

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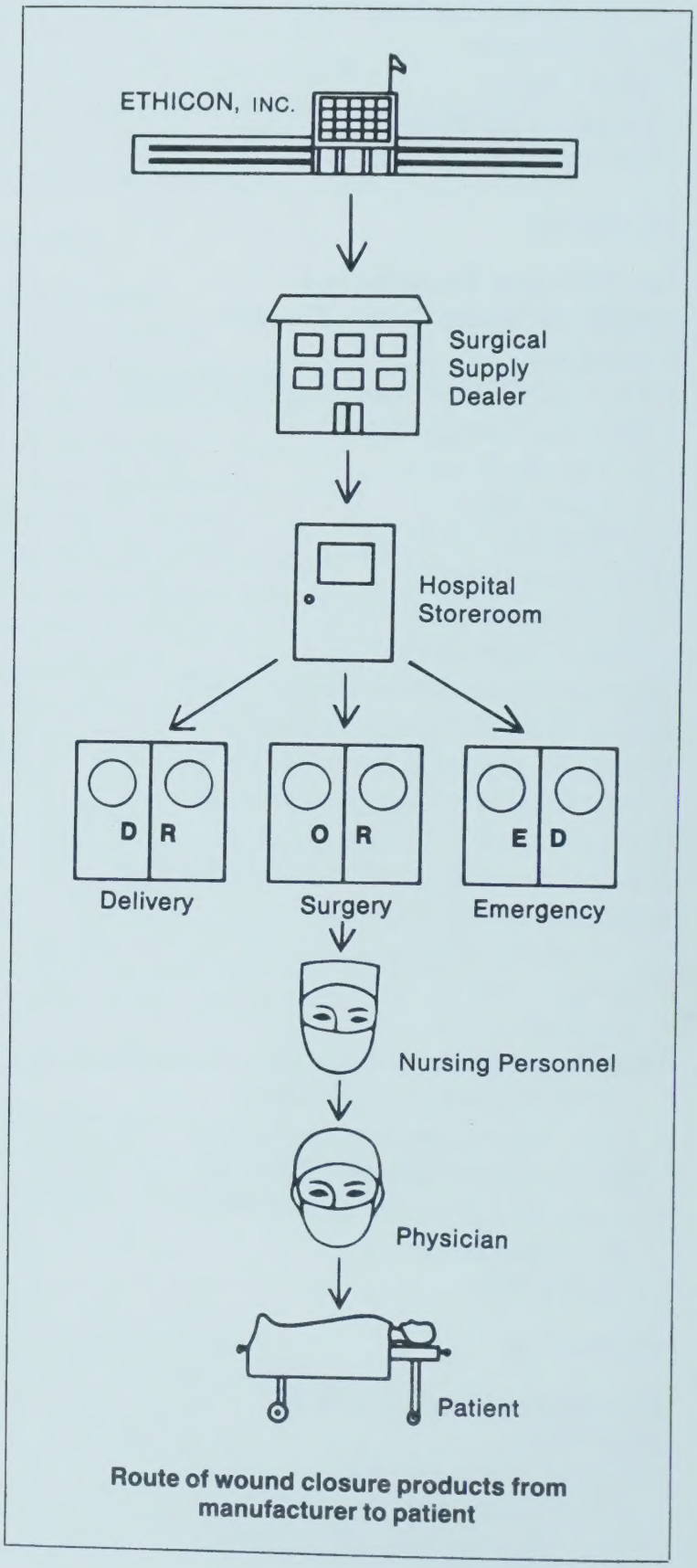


**Route of wound closure products from manufacturer to patient**

## Introduction to Wound Closure

The surgical or obstetrical patient or the victim of trauma is the ultimate "consumer" of ETHICON* products. Each of these patients has in common a wound, inflicted by design or by accident. Following ligation of severed blood vessels for hemostasis, the wound edges must be brought together and held in approximation until healing can take place. These are the primary functions of sutures and mechanical wound closure devices.

Usually the physician designates the size and type of ligation and wound closure materials to be used. The nurse or technician provides and prepares these materials according to the physician's preference.

Sutures and mechanical wound closure devices are used in three departments of the hospital. Extensive wound closure most frequently is performed in the operating room. Sutures are used to repair the birth canal in the delivery room. Minor lacerations may be closed in the emergency department. Operative procedures also are performed in ambulatory surgery centers and in doctors' offices.

This manual has been produced for all those who play a role in the care and handling of operative or traumatic wounds. Whether you are concerned with supplying, preparing or placing sutures and mechanical devices in the patient's tissues, may this *WOUND CLOSURE MANUAL* lead you to a greater understanding of this subject.

ETHICON, INC.

*Prepared under the direction of the Director of Educational Services,* ETHICON, INC.

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SECTION I

# Wound Healing

## WOUND CLOSURE MATERIALS

Severed tissues must be held in apposition until the healing process has endowed the wound with sufficient strength to withstand stress without mechanical support. Tissues may be approximated with sutures, staples, clips, or adhesive skin closure strips. The choice of wound closure materials and the technics of using them are prime factors in the restoration of continuity and tensile strength to the injured tissues during the healing process.

Tensile strength is defined as the greatest longitudinal stress a substance can bear without tearing apart. Tensile strength of normal body tissues refers to strength per unit area of tissue. Breaking strength involves a measurement of stress per unit width only. Burst strength denotes the amount of pressure necessary to rupture a viscus. The rate with which wounds regain strength in relation to biological alterations during the healing process must be understood as a basis for selecting the most appropriate wound closure material.

## WOUND HEALING

"Ideal healing is by regeneration, a process by which an injured part is replaced by the same tissue as that destroyed. Although some lower animals, such as the salamander, have striking regenerative ability, humans have, for the most part, lost this ability through the process of evolution. Only the epidermis *(the upper outermost layer of the skin)* and the mucosa *(the innermost layer of the intestine)* can regenerate; other tissues *(muscle, fat, fascia, blood vessels and so on)* heal by laying down collagen, the white protein that we know as scar tissue."[1]

The integrity of tissue may be violated either by intent to explore or remove pathology or to repair traumatic injury. Immediately the defense mechanisms inherent in normal body tissues are called into play to restore continuity and tensile strength. During the first few days, an inflammatory, defensive response causes an outpouring of tissue fluids, an accumulation of cells and fibroblasts, and an increased blood supply to the wound. Leukocytes and other cells produce proteolytic enzymes to dissolve and remove damaged tissue debris. After the debridement process is well along, fibroblasts begin to form collagen fibers in the wound. Collagen is a protein substance which is the chief constituent of connective tissue. Collagen fiber formation influences the tensile strength and pliability of the healing wound. In time, sufficient collagen is laid down across the defect so that the wound will withstand the normal forces put upon it. The time element varies with the type of tissue, the stresses or tension upon it, and other factors influencing wound healing.

### Types of Tissues

Skin and fascia are the strongest tissues, however, they regain tensile strength slowly during wound healing. Stomach and small intestine are much weaker, but heal rapidly. Variations in strength can occur within the same organ. For example, VanWinkle and Hastings reported comparative burst strengths of visceral organs. "Stomach was observed to be the weakest with the cecum a close second. Duodenum and ileum were significantly stronger than other parts of the gastrointestinal tract. Normal breaking strength of the colon increases from the ileocecal valve to the rectum." Their studies also indicate that the bladder has a strength comparable to that of the proximal part of the colon and can be considered one of the weakest organs in the body.[2]

Tissues can vary in strength depending on size and age of the patient. Allowance also must be made for variations in thickness of the tissues at various time periods. The thickness of the wound can vary by changing the water or cellular content without affecting the portion that gives the wound strength. Edema and induration, however, can affect the tensile strength of the wound.

The fiber arrangement within tissue affects the holding power of the wound closure materials. Because of the orientation of the fibers along the long axis of a tendon, for example, suture will tend to pull out at lower forces. An incision across muscle fibers versus a muscle splitting incision will influence the appropriate type of closure. The advantages of the transverse or oblique incision of the abdominal wall have been stressed in the literature. "The transverse or anatomic incision preserves the integrity of the fascial fibers of the important muscles of the abdominal wall, that is, external oblique,

1. Warren R (ed); *Surgery,* Philadelphia: Saunders, 1963, pp 1-21
2. VanWinkle W, Hastings JC: Considerations in the choice of suture material for various tissues, *Surg Gynecol Obstet 135:* 114, July 1972

internal oblique, and transverse. When these fascial fibers are divided transversely to their long axis, as in vertical incisions, the dynamic action of the muscles tends to pull the incision apart."[3]

### Stress and Tension on Wound

A cellular response occurs whenever foreign materials, including sutures and staples, are implanted in tissues. This foreign body tissue reaction varies from slight to moderate depending on the type of tissue and the material implanted *(see Table I, page 25)*. The reaction may be more marked if complicated by infection or trauma. The initial reaction is a reflection of the passage of the needle and suture or staples through the tissues. For example, after an incision has been closed, edema of the skin and subcutaneous tissues always ensues. Therefore, tight skin sutures or embedded staples can lead to patient discomfort and scarring secondary to ischemic necrosis.

All tissues must be closed with sufficient tension for approximation and elimination of dead space, but loose enough to prevent tissue strangulation and necrosis. Too tight a closure or closure under tension causes ischemia, a decrease of blood supply to the tissues.

Dead space is caused by separation of wound edges that have not been closely approximated or by air trapped between layers of tissue. Serum or blood may collect in a dead space, which predisposes to wound infection. A drain may be inserted or a pressure dressing applied to help obliterate dead space in the wound postoperatively.

Fascia can be placed under high tension when the patient coughs or strains to vomit, void or defecate. Abdominal wounds and others where high tension exists, such as tendons in the extremities, need support for two to three weeks or more.

### Other Influential Factors

The age and weight of the patient affect the speed of the healing process. Tissues in elderly patients and obese patients may heal slowly. Skin and muscle lose tone and elasticity as natural characteristics of the aging process. Excess fat may prevent securing a good closure. Fat is the most vulnerable of all tissues to trauma and infection because of its poor blood supply.

If the patient is undernourished, wound healing may be delayed. Deficiencies in carbohydrates, proteins, zinc and vitamins A, B and C can impair wound healing. Carbohydrates contribute to the healing process. Vitamin B is necessary for carbohydrate metabolism. Metabolized in the plasma, proteins have a major role in the support of the cellular activities essential to wound healing. Plasma proteins provide essential amino acids for collagen synthesis into scar formation. Although known to be important in collagen synthesis, the mechanism of vitamin A and zinc in wound healing is unknown. It is known that "zinc deficiency results in abnormal keratinization and reduced wound tensile strength and alters glycine incorporation into collagen."[4]

Dehydration also may delay wound healing. Changes in fluid and electrolyte balance can affect kidney function, cellular metabolism, oxygen concentration in the circulation, or hormonal function.

Healing generally is fastest in those areas having the greatest blood supply, for example, the face and neck. Blood supply is decreased in tissue following radiation in large doses. Healing can be impaired by any deficiency in blood and/or oxygen supply.

Other factors such as the amount of devitalized or dead tissue within the wound, the presence and types of foreign bodies, the nature and location of the wound, the local or general immune responses of the body, and the general condition of the patient are important considerations. Functional abnormalities in immune responses, such as an allergic reaction, or any agents that interfere with cellular metabolism, such as those used in chemotherapy, have a potentially deleterious effect on the healing process. Prolonged high dosages of steriods preoperatively, such as cortisone and progesterone, inhibit fibroplasia and formation of collagen.

Many patients are in less than excellent physical condition at the time of operation. Wound healing often will be delayed if the patient has a chronic disease, with associated anemia or leukopenia, diabetes or cirrhosis. Malignancies, debilitating injuries and systemic or localized infection also can adversely affect wound healing.

## SURGICAL PRINCIPLES

Several factors that favorably influence healing can be controlled to an extent by the surgical team during an operation in the operating room, by the obstetrical team during an episiotomy repair in the delivery room, or by the emergency team during the closure of a laceration in the emergency department. Most important to successful healing of wounds is maintenance of sterile and aseptic technic to prevent infection. This is a joint responsibil-

3. Lehman JA et al: Prevention of abdominal wound disruption, *Surg Gynecol Obstet 126:* 1236, June 1968
4. Powanda MC, Moyer ED: Plasma proteins and wound healing, *Surg Gynecol Obstet 153* (5): 749-750, Nov 1981

ity of the surgeon or other physician, surgical assistants, nursing personnel, anesthesiologists and anyone else who is allowed to enter the room during the procedure. Wound contamination due to failure of personnel to follow aseptic technic is one potential source of infection. It is probable that many patients are the source of their own infection since cultures made of the infected wound postoperatively often yield the same organisms found in the patient's nose, throat or elsewhere in the body. However, microorganisms carried by personnel may, at times, be the source of postoperative wound infection. Whatever its source, infection in the wound is a serious deterrent to healing.

The surgeon has other principles to consider in planning and carrying out the operative procedure. To promote optimum wound healing and to achieve the best possible results for the patient, the surgeon must keep these principles in mind.

1) The location, length and depth of the incision are individually planned and designed to achieve optimum exposure. A properly planned incision is just long enough to afford sufficient operating space. The direction of the incision may be a factor in wound healing. Wounds heal side-to-side, not end-to-end.
2) A clean incision is made through the skin with one stroke of evenly applied pressure on the scalpel. Sharp dissection is used to cut through other tissues. Careful consideration is given to underlying nerves, blood vessels and muscles to preserve as many as possible.
3) All tissues should be handled very gently and as little as possible throughout the operative procedure. Care must be taken in placing and handling retractors to prevent undue pressure on tissues. Excessive pressure and tension on tissues impairs circulation of blood, slows lymph flow, alters the local physiological state of the wound, and predisposes to microbial colonization. Reducing tissue trauma to a minimum aids the healing mechanism of the body.
4) Hemostasis not only prevents loss of the patient's blood, but provides as bloodless a field as possible for accurate dissection. Bleeding may occur from transected or penetrated vessels or a diffuse oozing from large denuded surfaces. Mass ligation of large areas of tissue may produce necrosis and prolonged healing time. Various mechanical, thermal and chemical methods are used to achieve hemostasis. It is important that complete hemostasis be achieved before a wound is closed to prevent hematoma formation. A hematoma or seroma in the incision prevents the direct apposition essential to the union of wound surfaces. These can act as a culture medium for microbial growth, leading to wound infection.
5) Preservation of blood supply is important in all tissues. Adequate debridement of all necrotic and devitalized tissue and removal of inflicted foreign bodies also are essential to healing, especially of traumatic wounds. Foreign bodies, such as dirt, metal or glass, increase the probability of wound infection.
6) Periodic irrigations with warm physiologic *(normal)* saline solution or covering exposed surfaces with saline-moistened sponges or laparotomy tapes helps avoid drying of tissues during long procedures.
7) Approximation of the tissues as nontraumatically as possible and with precision to eliminate dead space allows maximum opportunity for healing, and minimizes potential for wound disruption. The surgeon must evaluate each patient and choose the wound closure materials most likely to promote healing under each particular surgical circumstance. Tissue should be approximated without tension or strangulation to prevent necrosis.
8) Adequate immobilization of the approximated wound, but not necessarily the entire anatomic part, is mandatory for efficient healing and minimal scar formation.

## CLASSIFICATION OF WOUNDS

Operative wounds are classified as clean, clean-contaminated, contaminated, and dirty and infected. This standard classification is based on a clinical estimation of microbial contamination and the risk of subsequent infection.[5]

### Clean

A clean wound is a nontraumatic, uninfected operative wound that does not enter the respiratory, alimentary or genitourinary tracts or the oropharyngeal cavity. Clean wounds are usually elective. No inflammation is encountered. They are closed primarily and are not usually drained. No break in aseptic technic occurs during the procedure. Seventy-five percent of all operations fall within this category.

### Clean-Contaminated

A clean-contaminated wound has usual normal

5. American College of Surgeons, Altemeier WA et al (ed): *Manual on Control of Infection in Surgical Patients*, Philadelphia: Lippincott 1976, pp. 29-30

flora, but is an operative wound without unusual contamination. The wound may enter any part of the oropharyngeal cavity. The respiratory or alimentary tracts may be entered without significant spillage. The genitourinary or biliary tracts may be entered in the absence of infected urine or bile. An appendectomy and vaginal operations fall in this classification. Normally clean wounds contaminated by a minor break in aseptic technic also are classified as clean-contaminated.

### Contaminated

Contaminated wounds include soft tissue lacerations, open fractures, penetrating wounds and other fresh traumatic injuries. This classification also includes operative procedures in which gross spillage from the gastrointestinal tract occurs, and the genitourinary or biliary tracts are entered in the presence of infected urine or bile. Operations with a major break in aseptic technic, such as an emergency open cardiac massage, must also be classified as contaminated.

### Dirty and Infected

Dirty and infected wounds are those that are heavily contaminated or clinically infected prior to operation. These can include a perforated viscera, an abscess, or an old traumatic wound with retained devitalized tissue or foreign bodies. Microorganisms multiply rapidly and within six hours contamination can become infection.

## TYPES OF WOUND HEALING

The rate and pattern of wound healing differs in different tissues and under different circumstances. Injury elicits both metabolic and physiologic responses at the site of tissue damage and throughout the body. Three types of wound healing are recognized: first intention, second intention, third intention. Each has practical applications in the closure of surgical incisions or traumatic wounds.

### First Intention

Every person who closes a wound would like it to heal by first intention following primary union. Healing follows the initial closure of an incised, aseptic, accurately approximated wound with minimal edema and no serous discharge or local infection. An incision that heals by first intention does so in a minimum of time with no separation of the wound edges and with minimal scar formation.

In general, first intention wound healing consists of three distinct phases:

1) *Phase of acute inflammatory response:* from day zero to day five. Fluids containing plasma proteins, blood cells, fibrin and antibodies exude into the wound. At the surface, fibrin and other proteins dry, forming a scab that seals the wound from further fluid loss and from microbial invasion.

   Inflammation occurs within a few hours, causing swelling, pain, fever and redness around the wound. The fever heightens metabolism. The migration of leukocytes from dilated blood vessels accompanies the swelling. These white cells break down to remove cellular debris and ingest microorganisms and foreign material. The early phagocytes are mostly neutrophils. Then monocytes arrive at the wound site from more distant bone marrow. These become macrophages that ingest much of the remaining debris. They also produce proteolytic enzymes. Macrophages survive longer than the short-lived neutrophils.

   Epithelial repair begins by migration of basal cells downward over the incised dermis to close the surface of the wound. At the same time, fibroblasts come from nearby connective tissue to begin reconstruction of nonepithelial tissue.

   During the acute inflammatory phase, the wound is solely dependent on the closure material for strength. The wound does not gain appreciable tensile strength during this phase of healing. The adhesiveness of cells, blood vessels, globular proteins and fibrin weakly holds the wound edges together.

2) *Phase of fibroplasia:* from day five to day 14. "Fibrinogen accumulates at the site of injury for the first or second week after operation and, in the presence of enzymes released from the blood and cells in the surrounding tissues, forms fibrin. Fibrin increases the tensile strength of the wound and stimulates fibroblast proliferation and growth."[6] Fibroblasts *(fibrous tissue germ cells)* multiply rapidly, bridging wound edges and restoring continuity. The fibroblasts secrete collagen, a fibrous insoluble protein that forms into fibers in connective tissue. Deposition of collagen begins about the fifth day. This results in a rapid gain in tensile strength of the wound.

   Some plasma proteins localize specifically around the site of injury while others accumulate at the wound as a result of increased capil-

6. Powanda MC, Moyer ED: op cit, p. 751

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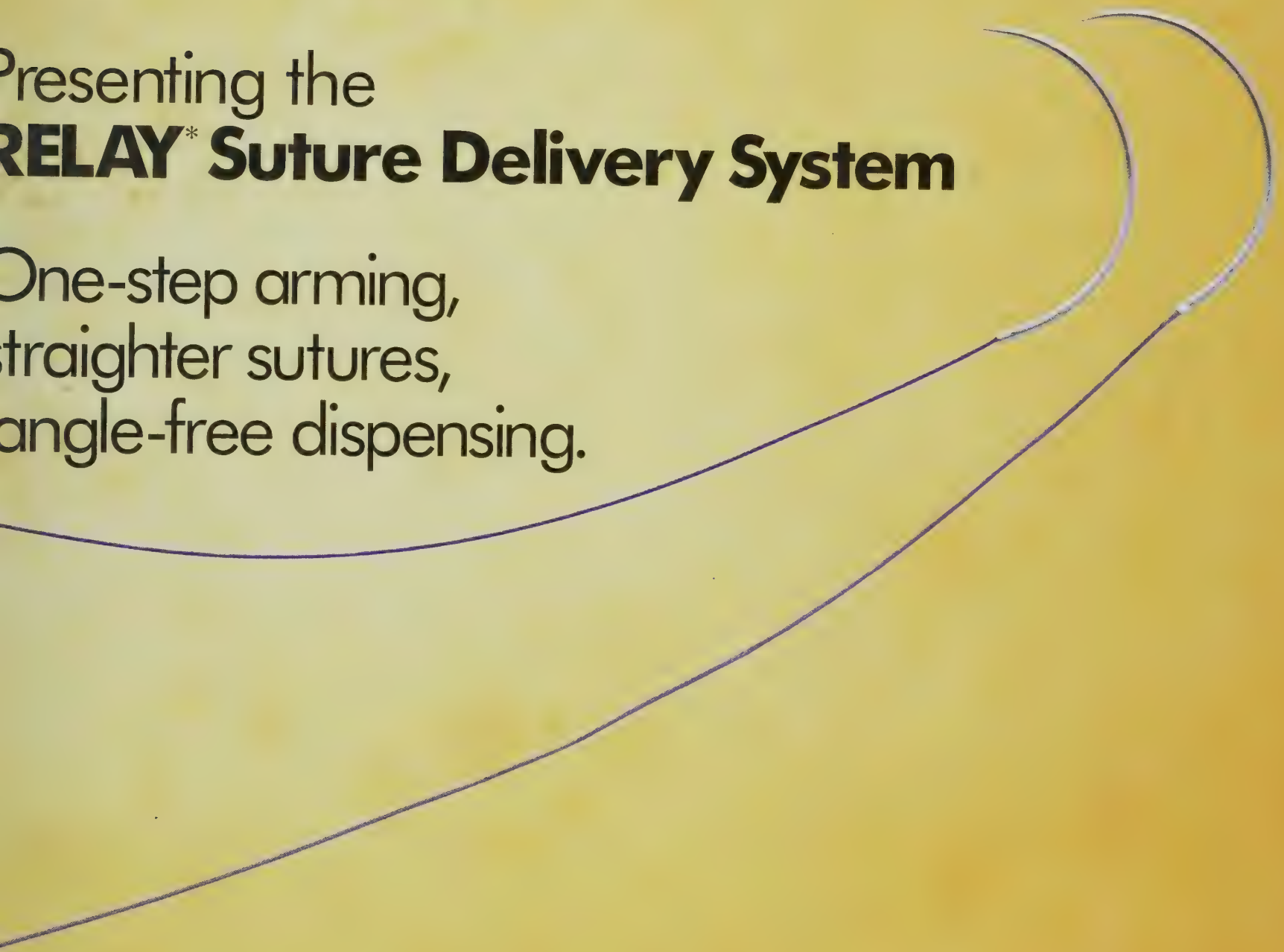

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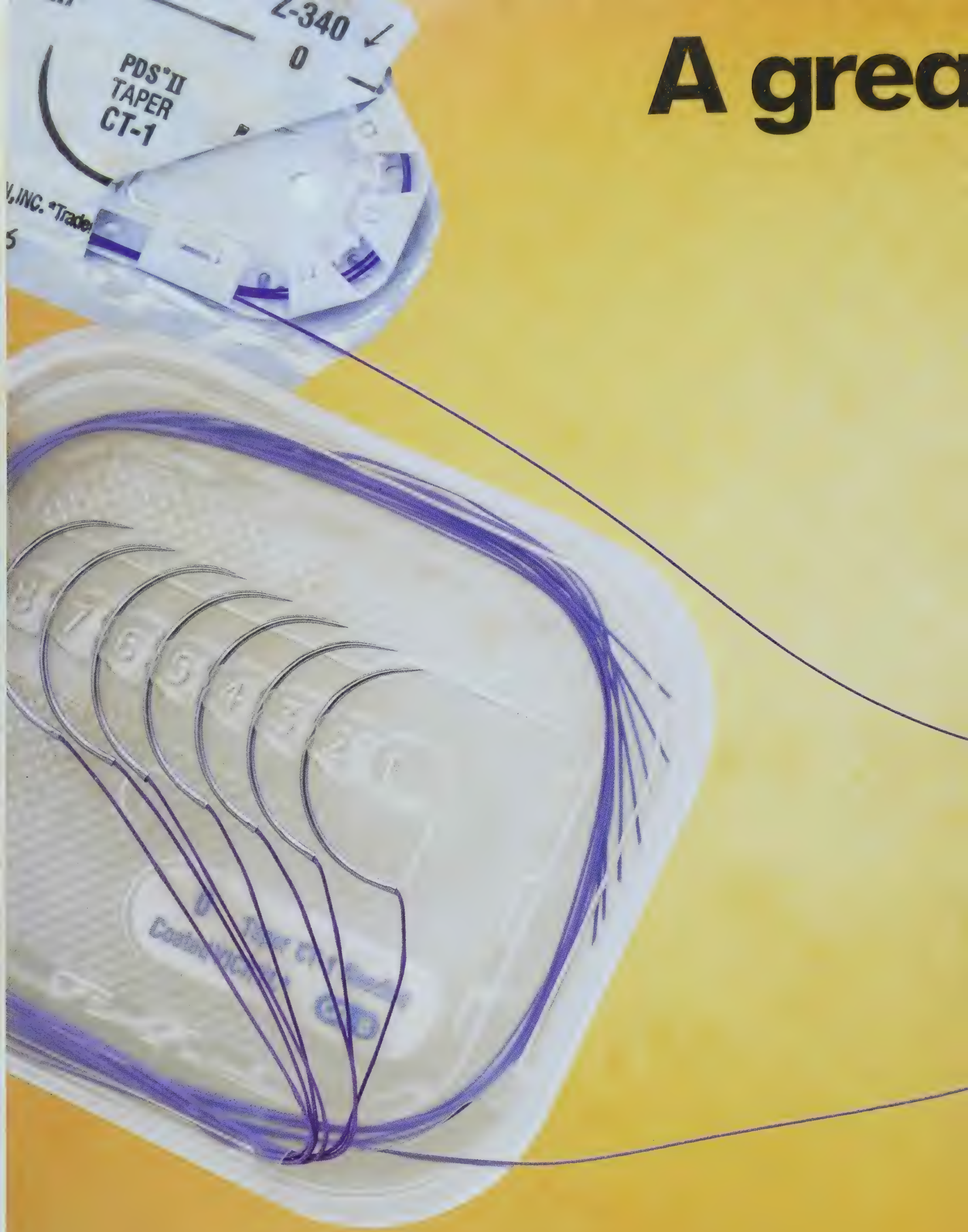


# A grea

lary permeability. Albumin, the major plasma protein, is made available to healing tissue in proportion to the extent of injury and inflammation. Albumin acts as an amino acid transport agent by binding significant amounts of amino acids, such as cysteine. The sulphur amino acids, cysteine in oxidized form in particular, are known to stimulate collagen synthesis. In addition to amino acids, albumin also binds zinc. Zinc plays a role in collagen cross-linking. Ceruloplasmin, a plasma glycoprotein, and the copper it carries also are essential to collagen formation. Cysteine is oxidized by ceruloplasmin. Copper is essential for the extracellular cross-linking and maturation of collagen and elastin. Acting in concert, these and other plasma proteins play a major role in the support of the cellular activities essential to the fibrous tissue synthesis stage of wound healing.[7]

In addition to collagen synthesis, other damaged components of connective tissue are replaced. The lymphatics rechannelize; the blood vessels form buds that anastomose into myriad loops. Granulation tissue that forms at this stage characteristically is translucent, mucinous, grayish red and bleeds readily if disrupted. Numerous capillaries develop to provide an adequate blood supply for nourishment of the fibroblasts. Many of these will disappear in the final stage of healing.

3) *Phase of maturation:* from day 14 until the wound is fully healed. No sharp distinction actually exists between the phases of fibroplasia and maturation. Healing begins rapidly in the phase of fibroplasia, then diminishes progressively. However, tensile strength continues to increase up to one year postoperatively. The collagen content remains constant, but the tensile strength increases from the reforming and cross-linking of the collagen fiber pattern. Scar formation occurs by deposition of fibrous connective tissue.

   In normal healing, wound contraction occurs over a period of weeks and months. As collagen density increases, vascularity decreases and the scar tissue grows pale.

### Second Intention

In healing by second intention, granulation tissue containing fibroblasts forms in the defect and closes it by contraction with secondary growth of epithelium. The mechanism is by wound contraction rather than primary union. In the presence of infection, excessive trauma, loss of tissue, or if approximation of tissues is not precise, the wound frequently fails to heal by primary union. The wound may be left open and allowed to heal from the bottom toward the outer surface. The healing process is delayed and scar formation is excessive. A weak union may be produced that can be conducive to incisional herniation post-healing.

### Third Intention

Also referred to as delayed primary closure, healing by third intention occurs when two surfaces of granulation tissue are brought together. Delayed primary closure is a safe method of repair of contaminated and dirty and infected traumatic wounds. It has been used extensively in military wounds and can be used with advantage in the treatment of some civilian injuries, i.e., vehicular accidents, gunshot and deep penetrating knife wounds, where tissue loss is extensive and potential for infection is great. These wounds are initially treated by debridement of nonviable tissues and left open.

"The fundamental basis for delayed primary closure is that the healing open wound gradually gains sufficient resistance to infection to permit an uncomplicated closure. The repairative process of open wounds which is associated with this resistance to infection is characterized by the development of capillary buds and young fibrous tissue which is referred to as a *granulation tissue.*"[8]

Optimal time for delayed closure is four to six days post-injury. When closure is undertaken, skin edges and underlying tissues must be accurately and securely approximated. A deeper and wider scar usually results from delayed healing by third intention.

## COMPLICATIONS IN WOUND HEALING

Whenever the integrity of tissues is violated, the patient is immediately at risk. The many factors that influence wound healing have been discussed. Despite observance of the surgical principles and appropriate technics in treating wounds, complications in wound healing will occur in some patients, delaying recovery. The two major complications are postoperative infection and/or wound disruption.

### Postoperative Infection

If, despite all precautions, a wound infection does

7. Powanda MC, Moyer ED: op cit, pp. 749-755

8. Edlich RF et al: *Fundamentals of Wound Management in Surgery: Technical Factors in Wound Management,* S. Plainfield, N.J.: Chirurgecom, 1977, p. 67

develop postoperatively, a specimen of the purulent drainage or tissue culture should be obtained. Adequate incision and drainage is of primary importance, with debridement of necrotic tissue as necessary. Without this surgical intervention, no course of antibiotic therapy will succeed alone. After the invasive organism is identified and sensitivity tested, appropriate antibiotic therapy can be initiated.

A wound infection results from the introduction of virulent organisms into the receptive wound of a susceptible host. Response may be localized or systemic. "A considerable number of surgical infections are mixed bacterial infections and those produced by a variety of bacteria, both aerobic and anaerobic, Gram-positive and Gram-negative. The incidence of various fungal and viral infections has been steadily increasing with the expanding clinical use of steroids, immunosuppressive agents and multiple antibiotic agents."[9]

Postoperative infections can be classified on the basis of the source or base of the infection, the associated anatomical and pathophysiological changes, and the microbial etiology. "The infected area is unlikely to resolve spontaneously and may cause suppuration, necrosis, gangrene, prolonged morbidity, other serious effects, or death if untreated."[10]

**Wound Disruption**

A potentially serious complication in the postoperative period is disruption of the wound. The term *dehiscence* indicates partial or total separation of layers of wound closure. *Evisceration* indicates protrusion of bowel through the separated edges of abdominal wound closure. This is an emergency situation. Replacement of the bowel and reclosure of the wound must be performed rapidly when evisceration occurs. When dehiscence occurs, the wound may or may not be reclosed, depending on extent of disruption and the individual surgeon's technic.

Wound disruption occurs more frequently in the older age group, but it may occur at any age, and in males more often than females. It is most common between the fifth and twelfth postoperative days.

The location and direction of the incision are considered to be important factors in wound disruption. Dehiscence occurs most frequently in vertical or nonanatomic incisions in the upper part of the abdomen. The relative tenseness of the muscles and fascia in this area, due to attachment to the thoracic cage, is a major factor. Consequently, the highest incidence of dehiscence occurs following gastric operations, operations on the biliary tract and intraabdominal cancer operations. Cancer by itself does not predispose to wound disruption, but it can lead to debility and hypoproteinemia. Hypoproteinemia may be a contributing factor in impaired wound healing and subsequent wound disruption.

Distention, vomiting and coughing increase intraabdominal pressure, which in turn increases tension on the wound. These are the major causes of evisceration prior to the fifth postoperative day.

"No single etiologic factor can account for all abdominal wound disruptions. Frequently, it is a combination of causes which ultimately leads to the complication. Increased intraabdominal pressure and lack of tensile strength in the wound are the basic reasons for dehiscence."[11] The type of incision, the type of wound closure material and the technic used for wound closure also are contributing causes. No wound will remain approximated with an inadequate closure technic or improper choice of wound closure material.

9. American College of Surgeons, Altemeier WA et al (ed): *Manual on Control of Infection in Surgical Patients*, op cit, p. 26
10. Ibid, p. 20
11. Lehman JA et al: op cit. p. 1240

SECTION II

# Suture Use

## WHAT IS A SUTURE?

A suture is a strand of material used to ligate *(tie)* blood vessels and to approximate *(sew)* tissues together. Used in the verb form, to suture is the act of sewing or bringing tissues together and holding them in apposition until healing has taken place.

The first written description of sutures used in operative procedures is recorded in the Edwin Smith papyrus, the oldest known surgical document. This piece of Egyptian literature is dated in the 16th century B.C. As far back in history as 2000 B.C., medical writings contain references to the use of strings and animal sinews for ligating and suturing.

Rhazes of Arabia was credited in 900 A.D. with first employing *kitgut* to suture abdominal wounds. The Arabic word "kit" means a dancing master's fiddle. In those days the musical strings of fiddles, called kitstrings, were made of sheep intestines. It has been speculated that Rhazes used these to suture. The term *catgut,* thought to have evolved from its origin as kitgut, was used for many years in reference to suture material made from sheep or beef intestines. The more accurate term *surgical gut* has replaced the term catgut.

Many different materials have been used as ligatures and sutures through the centuries: gold, silver and tantalum wire, silk, silkworm gut, linen, cotton, horsehair, the tendons and intestinal tissue of various animals, to name only a few. These and other materials have undergone varied treatments and refinements in an effort to develop the suture materials that are most effective in accomplishing wound healing. *(Refer to Section III for discussion of current suture materials.)*

The precise approximation of the patient's tissues with sutures for maximum healing in minimal time requires the cooperative efforts of the suture manufacturer, nursing personnel and the surgeon.

1) The manufacturer must endeavor to produce suture materials possessing the greatest tensile strength consistent with size limitations and assuring adequate handling properties. The manufacturer must package these materials in a manner which presents them at point of use in excellent condition.
2) Nursing personnel must store, handle and prepare sutures in such a manner that sterility is maintained and that the integrity and strength of each strand is maintained until it is handed to the surgeon.
3) The surgeon must select and place appropriate suture materials in the tissues in a manner consistent with the principles that promote optimum wound healing.

## BIOLOGICAL RESPONSE TO SUTURE MATERIALS

The selection of suture material by the surgeon must be based on a sound knowledge of the healing characteristics of the tissues to be approximated, the condition of the wound being closed, and the probable postoperative course of the patient *(refer to Sections I and IV)*. The surgeon also must have knowledge of the physical and biological properties of the suture material.[1]

Adequate suture tensile strength is required for wound closure. However, a suture usually need be no stronger than the tissues that are sutured. To minimize tissue reaction to sutures, the smallest size suture consistent with the needed holding power is desirable.

If uncomplicated by infection or trauma, the acute cellular tissue response to the suture material changes in about three days after implantation. The original population of neutrophils is replaced by predominantly monocytes, plasma cells and lymphocytes. Small sprouts of fragile blood vessels infiltrate the area, and eventually fibroblasts and connective tissue proliferate. Enzyme histochemistry has demonstrated that all the cellular changes are accompanied by the presence of a variety of enzyme patterns. Cellular enzyme activity is an important factor associated with all foreign body reactions, whether a mild reaction elicited by most suture materials, or the more severe tissue reactions associated with irritant materials. The level of lysosomal enzyme synthesis and function in macrophages is associated significantly with their phagocytic activity.

"Assuming the same technic, tissue and other reactive factors such as absence of infection, the reaction will be the same for all sutures during the first five to seven days, if not longer."[2] All suture materials are foreign bodies, but some are more inert *(less reactive)* than others in the later phases of wound healing.

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1. VanWinkle W, Salthouse TN: *Biological Response to Sutures and Principles of Suture Selection,* Somerville, NJ: ETHICON Research Foundation, 1976
2. Postlethwait RW et al: Human tissue reaction to suture, *Annals Surg 181* (2): 144, Feb 1975

## ORIGIN OF SUTURE PREFERENCE

Each surgeon decides which suture material/s will be used during the operation. Most surgeons have a basic *suture routine*, a preference for certain material/s they use unless circumstances dictate otherwise. When a particular suture material is used repeatedly, surgeons acquire proficiency and speed in handling it. They may prefer to use this material throughout their surgical career.

Often the surgeon is a "product of his or her upbringing." The teaching institution where the physician was a resident, or the chief under whom he or she trained, can or may exert a lasting influence on suture material preference. Probably the classic example of the influence of a professor and surgeon on the suture material preference and technic of his students is that of Dr. William S. Halsted. Dr. Halsted preferred surgical silk suture. He spent many years teaching students of surgery at Johns Hopkins Hospital and Medical School, Baltimore, Maryland, how to use silk correctly. The principles and technic for use of silk advocated by Dr. Halsted in the late 1800s and early 1900s remain valid.

## HALSTED SUTURE TECHNIC

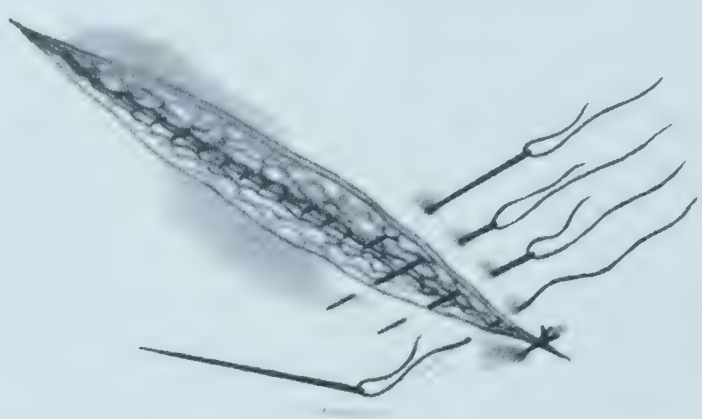
Halsted advocated using the finest gauge silk consistent with the tissues to be sutured. He said that the total volume of foreign body and its subsequent reaction is greater with one large rather than two or more fine strands. He recommended fine stitches placed close together. He advised cutting silk sutures close to knots to minimize the amount of foreign material left in the wound and to decrease tissue reaction.

Halsted used short suture strands and discarded each needle after use. He sometimes used more than 100 needles during an operation. He preferred straight needles for skin closure *(Fig. 1)*.

Halsted was meticulous about hemostasis. He believed that each blood vessel, however small, should be ligated or sutured for exact control of postoperative bleeding. Blood clots can push wound edges apart or serve as a culture medium for microorganisms.

Halsted urged the use of interrupted rather than continuous sutures. He reasoned that in the presence of infection, continuous suture lines of braided silk would permit microorganisms to travel the length of the suture, infecting the entire area. He believed that if infection is present, interrupted suture lines are more apt to permit the body to wall off or isolate the offending microorganisms.

**Fig. 1 Dr. William Halsted preferred fine milliner needles with 15″ silk sutures for skin closure**



Halsted particularly stressed refinements in operating procedures, gentle handling of tissues, avoidance of tension on sutures and tissues, and careful and unhurried surgery. Dr. Halsted and his associates obtained quick and uncomplicated convalescence of patients which was talked of throughout the world at that time.

Halsted's principles are, in general, still highly regarded. However, they were based on the use of the only suture materials available to him, silk and surgical gut. With the advent of synthetic monofilament sutures, repeated controlled clinical studies have shown that mass abdominal wound closure technics with continuous running sutures are faster and not likely to lead to the complications of dehiscence and evisceration.

## COMMON SUTURING TECHNICS

Suture is an all-inclusive term for any strand of material used for ligating or approximating tissues. Meticulous hemostasis and precise approximation are essential to uneventful healing. Numerous variations are possible to place sutures and tie knots.

### Ligatures

A suture tied around a vessel to occlude the lumen is called a *ligature* or *tie*. It may be used to effect hemostasis or to close off a structure to prevent leakage.

1) *Free tie* is a single strand of material handed to the surgeon or assistant to ligate a vessel. A hemostat is placed on the end of the structure and the suture tied around the vessel under the *tip* of the hemostat. The knot is tightened by the surgeon's fingers or with the aid of forceps, taking care to avoid instrument damage to the suture.

2) *Stick tie*, also referred to as a *suture ligature* or *transfixion suture*, is a strand of suture material attached to a needle. The needle is used to anchor the strand in tissue before occluding a deep or large vessel. The strand must be of sufficient length to allow the surgeon to tighten the first knot.

**Primary Suture Line**

The *primary suture line* refers to those sutures that hold wound edges in approximation during healing by first intention. This line may have one continuous strand of suture material or a series of interrupted suture strands. A variety of technics are used to place sutures in tissues, but all utilize a surgical needle attached to the suture strand for repeated passes through tissue.

*Continuous Suture*

A series of stitches are taken with one strand of material tied only at each end of the strand *(see Fig. 2)*. This may be referred to as a *running stitch*. A continuous suture line may be placed rapidly and is strong because tension is evenly distributed along its full length. "It does not strangulate the tissue as long as it is placed with *firm*, not *tight*, tension."[3]

Continuous suture technic leaves less foreign body mass in the wound. However, if a continuous suture breaks, the whole line disrupts. If this technic is used, monofilament suture material may be desirable in the presence of infection. The interstices of a multifilament material will act as a harbor for the infecting organism. Monofilament material eliminates this possibility.

Use of continuous stitches varies with the tissue and the desired result. A continuous one layer mass closure may be used to close peritoneum and/or fascial layers of the abdominal wall to provide a temporary seal. "The tensile strength of the wound is probably related to the total mass of collagen included in the suture."[4]

*Interrupted Sutures*

Each stitch is tied and cut after insertion of the suture strand through the tissue *(see Fig. 3)*. This consumes more operating time than a continuous suture, but is the most widely used technic. If an interrupted suture should break or loosen, the remaining sutures may still hold the wound together. In the presence of infection, it is thought that microorganisms are less likely to travel along the primary suture line of interrupted stitches.

3. Martyak SN, Curtis LE: Abdominal incision and closure: A systems approach, *Am J Surg 131:* 478, April 1976

4. Ibid

**Fig. 2 Continuous suture**

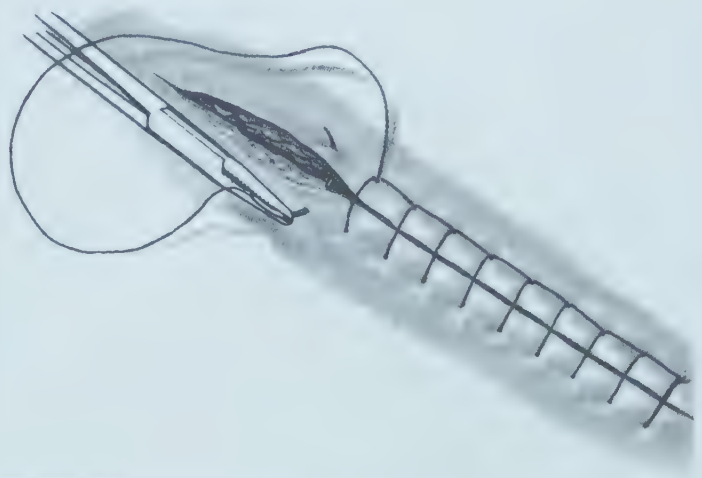
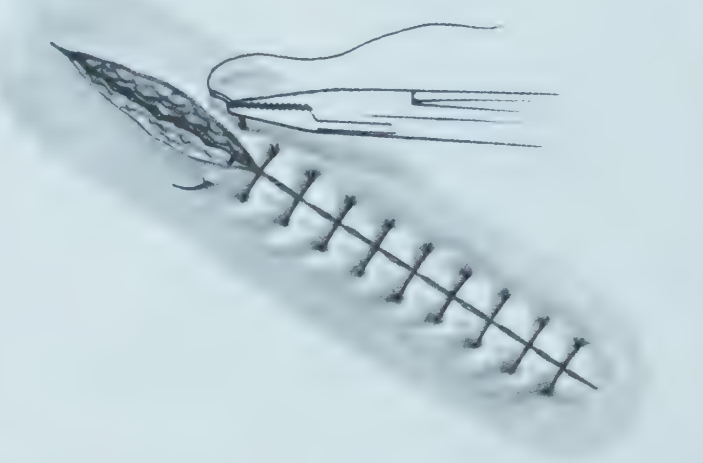


**Fig. 3 Interrupted sutures**



*Buried Sutures*

Sutures placed completely under the epidermal layer of the skin are considered "buried." They are not removed postoperatively. Buried sutures may be continuous or interrupted.

*Purse-string Suture*

A continuous suture is placed around a lumen and tightened, like a drawstring, to invert the opening. A purse-string suture may be placed around the stump of the appendix, in the bowel to secure an intestinal stapling device, or in an organ prior to insertion of a drainage tube.

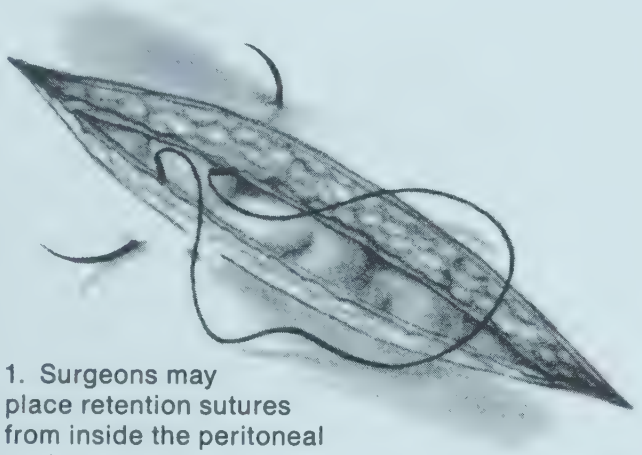
*Subcuticular Suture*

A continuous suture may be placed in the subcutaneous tissue, beneath the epithelial layer, in a line parallel to the wound to close the skin. The suture must be anchored at one end of the wound with a conventional tie or a perforated lead shot. Short lateral stitches are taken the length of the wound. The suture is drawn taut and the distal end anchored in the same manner as the proximal end.

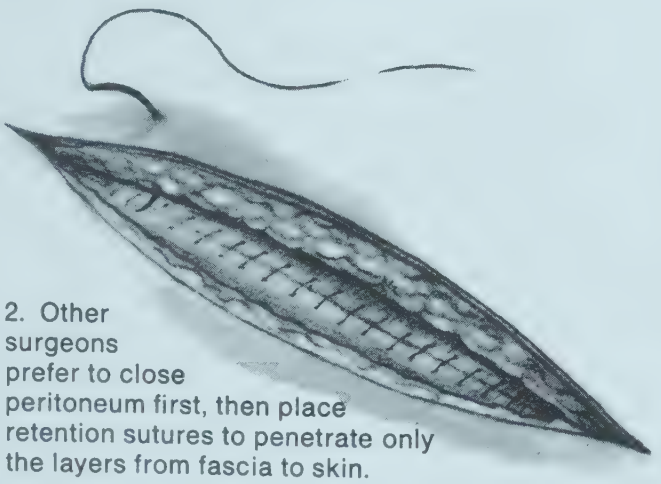
### Secondary Suture Line

The *secondary suture line* refers to those sutures placed to reinforce and support the primary suture line, obliterate dead space, and prevent fluid accumulation in an abdominal wound during healing by first intention. Placed about two inches away from each edge of the wound, the tension exerted lateral to the primary suture line contributes to the tensile strength of the wound. Sutures used for this purpose are referred to as *retention, stay* or *tension* sutures. These sutures also are used to support wounds for healing by second intention and for secondary closure following wound disruption for healing by third intention. Two types of closure are used for placement of retention sutures. *(Fig. 4).*

**Fig. 4 Retention sutures**



1. Surgeons may place retention sutures from inside the peritoneal cavity through to the skin.



2. Other surgeons prefer to close peritoneum first, then place retention sutures to penetrate only the layers from fascia to skin.

#### *Through-and-Through Retention Sutures*

Some surgeons place retention sutures from inside the peritoneal cavity through all layers of the abdominal wall, including the peritoneum. These "through-and-through" sutures are inserted before the peritoneum is closed. A simple interrupted or a figure-of-eight stitch is used. The wound is then closed in layers for a distance of about three-fourths the length. The retention sutures in this area are drawn together and tied. It is important that a finger be placed within the abdominal cavity to prevent strangulation of the viscera in the closure. The remainder of the wound is then closed in a similar manner.

#### *Buried Coaptation-Retention Sutures*

Other surgeons prefer to close the peritoneum with interrupted sutures alternately with the retention sutures that are placed to penetrate the other layers from fascia through skin. The retention sutures are placed approximately two centimeters apart in the posterior rectus sheath and peritoneum in the so-called "far-and-near" or "far-near-near-far" fashion. The remainder of the wound is closed in layers, and the retention sutures tied.

## PLACEMENT OF STITCHES

Many types of stitches are used for both continuous and interrupted suturing. Some of the more common ones are illustrated in *Fig. 6.* Equal bites of tissue should be taken on each side of the wound. "The distance of the needle insertion from the edge of the wound is dependent on the tissue being sutured...from one to three centimeters usually. The distance from one suture to the next should be approximately the same as the distance from the edge of the wound to the suture."[5]

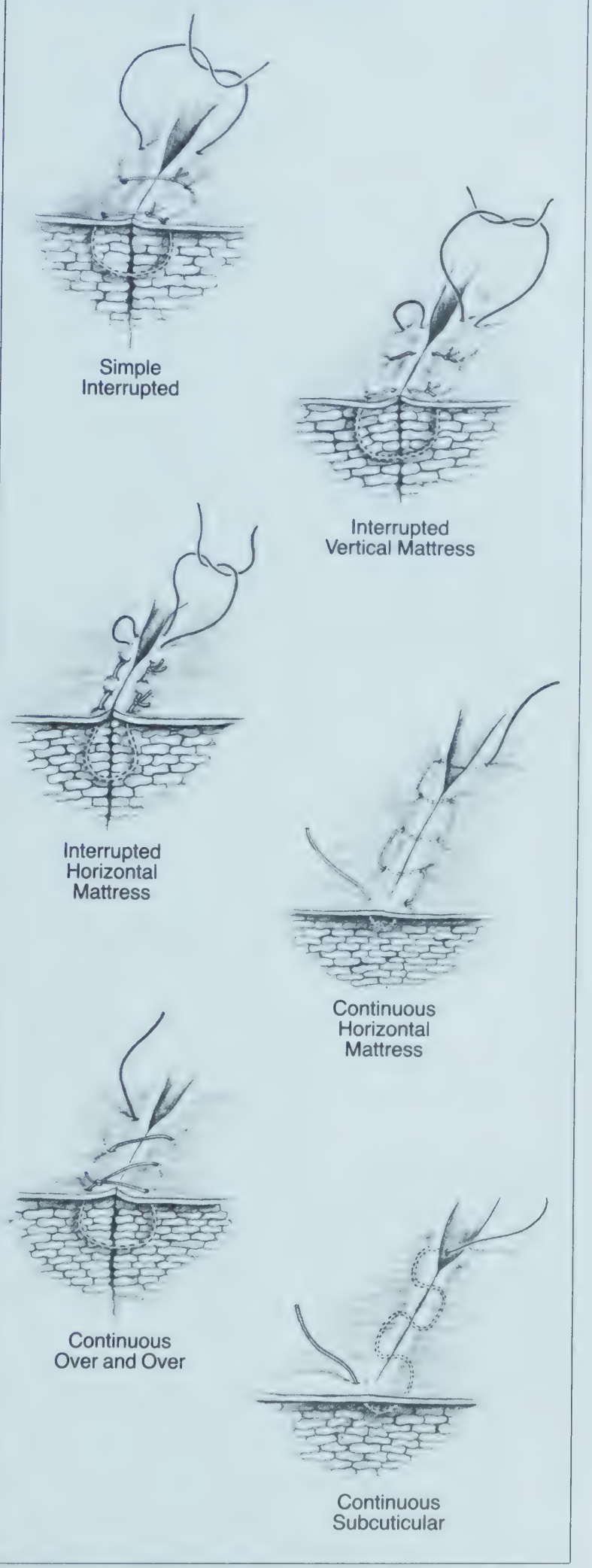
Most tissues will heal when the edges are held in apposition. In some circumstances, the tissues should be either inverted or everted. For example, the mucosa is inverted in a sutured gastrointestinal anastomosis, apposing serosa to serosa. Skin edges may be everted prior to the placement of sutures. *Fig. 5* lists the types of stitches most commonly used for approximating tissue.

**Fig. 5 Commonly used types of stitches**

| Continuous suture | Interrupted sutures |
|---|---|
| To appose skin and other tissue | |
| Over-and-over<br>Vertical mattress<br>Horizontal mattress<br>Subcuticular | Over-and-over<br>Vertical mattress<br>Horizontal mattress |
| To invert tissue | |
| Lembert<br>Cushing<br>Connell | Lembert<br>Halsted<br>Purse-string |
| To evert tissue | |
| Horizontal mattress | Horizontal mattress |

5. Nealon TF: *Fundamental Skills in Surgery,* 3rd ed, Philadelphia: Saunders, 1979, p. 47

**Fig. 6 Common suturing technics**




## KNOT TYING

Of the more than 1400 different types described in the *Encyclopedia of Knots,* only a few knots are used in modern surgery. But it is of paramount importance that each knot placed in a suture be perfect. It must hold with proper tension.

The knot the surgeon prefers to use to secure the suture will vary according to the material used and the location, depth and purpose of the suture. Knots must be tied with a technic appropriate for the tissues to be sutured or ligated, and only tight enough to serve their purpose without slipping. Postoperative edema must be anticipated. Generally, synthetic suture materials have very smooth surfaces. They may require a different number of throws to achieve knot security than the natural fibers. *(Refer to Section III for additional information on knot security.)*

Some general principles govern the tying of all knots, regardless of the suture material to be tied.

1) The completed knot must be firm, and tied so that slippage will be virtually impossible. The simplest knot is the most desirable.
2) The knot must be small and the ends of the suture cut as short as possible with a given material to minimize foreign body tissue reaction.
3) A sewsaw motion, or the sawing of one strand down over another until the knot is formed, may materially weaken sutures to the point that they may break when the second throw is made.
4) Avoiding excessive tension leads to successful use of finer gauge materials. If the two ends of the suture are pulled in opposite directions with uniform rate and tension, the knot may be tied securely with less possibility of breakage.
5) Clamps and hemostats should never be placed on any portion of the suture which will remain *in situ.* Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.
6) Sutures for approximation, rather than hemostatic purposes, should not be tied too tightly as this causes tissue strangulation.
7) After the first loop is tied, it is necessary to maintain traction on one end of the strand for control to avoid loosening.
8) Extra throws do not add to the strength of a properly tied knot; they only contribute to its bulk.

## CUTTING SUTURES

To cut sutures, the tip of the scissors are run lightly down the strand to the knot. The ends of surgical gut are cut relatively long, a ¼ inch *(6 mm)* from the knot. Other materials are cut close to the knot about 3 mm, to minimize amount of foreign material left in the wound and decrease tissue reaction. Before the suture is cut, the tips of the scissors must be in sight to avoid inadvertently cutting tissue. The ends of the suture are removed from the operative site as they are cut.

## SUTURE REMOVAL

Nonabsorable skin sutures are always removed postoperatively. The length of time sutures remain in place is variable. "A general rule regarding time is as follows:

| | |
|---|---|
| 1) Skin about face and neck | 2 to 5 days |
| 2) Other skin sutures | 5 to 8 days |
| 3) Retention sutures | 10 to 14 days |

6. Ibid, p. 48
7. Krizek TJ, Hoopes JE (ed): *Symposium on Basic Science in Plastic Surgery,* Vol 15, St. Louis: Mosby, 1976, p. 87

The difference in time is related to the rate of healing in individual areas and the purpose for which the sutures were initially placed."[6] The surgeon decides when the sutures should be removed.

### Technic of Suture Removal

Sutures are removed using aseptic and sterile technic. A sterile suture removal tray is prepared for the procedure.

1) Cleanse the area with an antiseptic. Hydrogen peroxide can be used to remove dried serum encrusted around the sutures.
2) Pick up one end of the suture with thumb forceps. Cut the suture on one side as close to the skin as possible, where it dips beneath the skin.
3) Gently pull the suture out through the other side while holding the suture with the forceps. The suture should be removed without pulling any portion that has been outside the skin back through the skin.

Sutures should be removed "before the epithelium has migrated into deeper parts of the dermis. To prevent widening of the scar, the wound edges may be taped."[7]

SECTION III

# Suture Materials

## CHARACTERISTICS OF SUTURE

"The ideal suture would consist of material which permits its use in any operation, the only variable being the size as determined by the tensile strength. It should handle comfortably and naturally to the surgeon. The tissue reaction stimulated should be minimal and should not create a situation favorable to bacterial growth. The breaking strength should be high in small caliber. A knot should hold securely without fraying or cutting. The material must be sterile. It should not shrink in the tissues. It should be nonelectrolytic, noncapillary, nonallergenic and noncarcinogenic. Finally, after most operations the suture material should be absorbed with minimal tissue reaction after it has served its purpose."[1]

Because *the ideal suture* described by Postlethwait does not yet exist, no one suture material meets the criteria as an *all purpose* suture. However, the surgeon must be assured of the following qualities:

1) High uniform tensile strength, permitting use of finer sizes
2) Consistently uniform diameter per size
3) Pliability for ease of handling and security of knots
4) Predictable performance
5) Optimum tissue acceptance, free of irritating substances or impurities, as inert as possible
6) Sterile, ready to use.

The requirement for wound support varies in different tissues from a few days for muscle, subcutaneous tissue and skin to weeks or months for fascia and tendon to long-term stability as for a vascular prosthesis. The surgeon must be aware of these differences in the healing rates of various tissues and organs. In addition, factors present in the individual patient, such as infection, debility, respiratory problems, obesity, etc., can influence the postoperative course and the rate of healing.

Suture selection should be based on a knowledge of the physical and biologic characteristics of the material in relationship to the healing process. The surgeon wants to insure that a suture will retain its strength until the tissue regains enough strength to keep the wound edges together on its own. In some tissue that might never regain preoperative strength, the surgeon will want suture material that retains strength for a long time. If a suture is going to be placed in tissue that heals rapidly, the surgeon may prefer to select a suture that will lose its tensile strength at about the same rate as the tissue gains strength and that will be absorbed by the tissue so that no foreign material remains in the wound once the tissue has healed. With all sutures, acceptable surgical practice must be followed with respect to drainage and closure of infected wounds. The amount of tissue reaction caused by the suture may encourage or retard the healing process.

When all these factors are taken into account, the surgeon has several choices of suture materials available. Selection can then be made on the basis of familiarity with the material, its ease of handling and other subjective preferences.

## TYPES OF SUTURE MATERIALS

Regardless of its nature, suture material is a *foreign body* to the human tissues in which it is implanted. Attempts are made by tissue enzymes, those complex substances within body cells, to rid themselves of the presence of a foreign substance. One of the capabilities of enzymes is to attack and break down an absorbable suture strand. Eventually the strand will be dissolved or digested. All suture material which is digested by body enzymes or hydrolyzed by tissue fluids is called *absorbable.*

Tissue enzymes cannot dissolve some suture materials. These are called *nonabsorbable.* The strand is encapsulated or "walled off". Nonabsorbable sutures ordinarily remain where they are *buried* within the tissues. When used exteriorly for skin closure, they must be removed postoperatively.

Sutures can conveniently be divided into two broad groups: absorbable and nonabsorbable. Absorbable sutures can be associated as *temporary;* most nonabsorbables are *permanent.* A further subdivision is useful: monofilament and multifilament. A *monofilament* suture is made of a single strand. It resists harboring microorganisms, and it ties down smoothly. A *multifilament* suture consists of several filaments twisted or braided together. This gives good handling and tying qualities. However, variability in knot strength among multifilament sutures might arise from the technical aspects of the braiding or twisting process.

1. Postlethwait RW: *Wound Healing in Surgery,* Somerville, NJ : ETHICON, INC., 1971, pp. 8-9

## SIZES AND TENSILE STRENGTH

The sizes and tensile strengths for all suture materials are standardized by specific regulations. Size denotes the diameter of the material. Stated numerically, the more zeroes (0's) in the number, the smaller the size of the strand. As the number of 0's decreases, the size of the strand increases. The 0's are designated as 5-0, for example, meaning 00000 which is smaller than a size 4-0. The smaller the size, the less tensile strength the strand will have. Tensile strength of a suture is the measured force in pounds that the strand will withstand before it breaks when knotted. *(Refer to Knot Pull Tensile Strength Chart on page 96).*

The accepted surgical axiom that the tensile strength of any suture need never exceed the tensile strength of the tissue it holds is responsible for the utilization of the smaller sizes of sutures. According to VanWinkle and Hastings, "Sutures should be at least as strong as normal tissue through which they are placed. If the tissue reduces suture strength with time, the relative rates at which the suture loses strength and the wound gains strength are important. If the suture biologically alters the healing process, these changes must be understood."[2]

Tissue reaction and a cellular response occurs whenever foreign material is implanted in tissue. When the smallest appropriate size suture is used, there is less tissue trauma from the suture itself and its passage through tissue. Fine size, closely placed sutures, decrease the possibility of dead space within the wound.

## ABSORBABLE SUTURES

The United States Pharmacopeia (U.S.P.) defines an absorbable surgical suture as a "sterile strand prepared from collagen derived from healthy mammals or a synthetic polymer. It is capable of being absorbed by living mammalian tissue, but may be treated to modify its resistance to absorption. It may be impregnated or coated with a suitable antimicrobial agent. It may be colored by a color additive approved by the Federal Food and Drug Administration (F.D.A.)"[3] *Fig. 7* lists the absorbable suture materials and gives the basic raw material from which each is manufactured.

Two important characteristics describe the *in vivo* performance of absorbable sutures: first, *tensile strength retention*, and second, the *absorption rate*. Specific patient conditions, such as increased body temperature, presence of infection, protein deficiency, etc., are not controllable by the suture manufacturer. These conditions may enhance a rapid decline in tensile strength and produce a more rapid absorption of sutures. In any case, absorbable sutures should not be used where extended approximation of tissues under stress is required.

**Fig. 7 Absorbable suture: Basic raw materials**

| Suture | Raw Material |
|---|---|
| Surgical Gut<br>Plain<br>Chromic | Submucosa of sheep intestine or serosa of beef intestine |
| Collagen<br>Plain<br>Chromic | Flexor tendon of beef |
| Polyglactin 910<br>Uncoated †<br>Coated ‡ | Copolymer of glycolide and lactide with polyglactin 370 and calcium stearate, if coated |
| Polyglycolic acid | Homopolymer of glycolide |
| Polydioxanone § | Polyester of poly (p-dioxanone) |

†VICRYL* (polyglactin 910) Suture
‡Coated VICRYL* (polyglactin 910) Suture
§PDS* (polydioxanone) Suture
*Trademarks of ETHICON, INC.

It is important to realize that the rate of tensile strength loss and the rate of suture absorption are separate events. For example, a suture can lose tensile strength rapidly in tissue and yet absorb slowly. Or it may retain very adequate tensile strength through the vital time of wound healing and then absorb rapidly. *Fig. 8* shows *in vivo* breaking strength retention and absorption profiles of absorbable sutures.

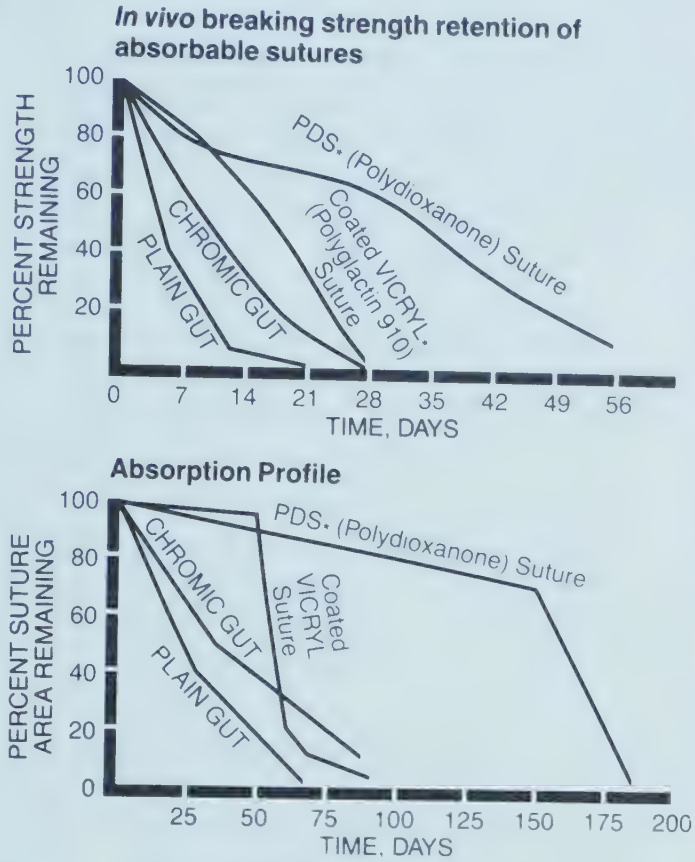
The absorption process is manifested by a gradual, almost linear loss of tensile strength over the first several weeks post-implantation. This is followed, often with considerable overlap, by the second stage of absorption which is loss of suture mass. During these periods, leukocytic cellular responses occur that serve to remove cellular debris as well as suture material from the line of tissue approximation.

### Natural Collagens

SURGICAL GUT. Absorbable surgical gut sutures are classified as either plain or chromic. Both types consist of processed strands of highly purified collagen, but chromic gut is processed to provide

2. VanWinkle W Jr, Hastings JC: Considerations in the choice of suture material for various tissues, *Surg Gynecol Obstet 135:* 113, July 1972
3. The United States Pharmacopeia, Twentieth Revision, Official from July 1, 1980

Fig. 8




Data on file ETHICON Research Foundation

greater resistance to absorption. Modern manufacturing processes provide sutures uniform in size and strength. The percentage of collagen in the suture directly determines the tensile strength of the suture and its ability to be absorbed by the body without adverse reaction. Noncollagenous material can cause a reaction that may be an irritation and even rejection of the suture. In contrast, the more pure collagen the suture has throughout length of the strand, the less the amount of foreign material in the wound. ETHICON* surgical gut sutures are 97-98 percent pure protein ribbons of gut.

To meet U.S.P. specifications, processed ribbons of the submucosa layer of sheep intestine or the serosa layer of beef intestine are electronically spun and polished into virtually monofilament strands of various sizes, with minimum and maximum limits on diameter for each size. The TRU-GAUGING process produces a uniform diameter along the full length of every strand with no high or low spots; the accuracy is within .0002 inch. High or low spots can cause the suture to fray or chatter when knots are tied down. The result can be a knot that is not positioned properly or tied securely. All protein-based absorable sutures have a tendency to fray when tied. However, the TRU-GAUGING process assures uniform high tensile strength, virtually eliminating the possibility of fraying and breaking. Due to the unexceeded strength and surface smoothness of ETHICON surgical gut, the surgeon can "snug down" the suture knot to achieve optimum knot tension. Tensile strength is measured on the basis of knot strength. Minimum knot pull strengths are specified for each size.

The rate of absorption is determined by the type of surgical gut, type and condition of the tissue involved and the general health status of the patient. Surgical gut is used in the presence of infection although it may be absorbed more rapidly under this condition. Surgical gut suture absorption is mediated through cellular and tissue proteases. When implanted in the body, surgical gut is attacked by the white blood cells which secrete enzymes, which in turn *digest* the gut and cause it to lose strength and absorb. Biologic conditions in patients cause the rate of loss of tensile strength and the rate of absorption to vary.

Plain gut is not treated with chromium salts and is digested within 70 days by the body enzymes. However tensile strength is maintained for only 7 to 10 days. The surgeon may choose to use it in tissues which heal rapidly and require minimal support during healing. Plain gut is used primarily for ligating superficial blood vessels and suturing subcutaneous fatty tissue.

Fast absorbing plain surgical gut is specially heat treated to speed up tensile strength loss and absorption. It is designed for *epidermal* suturing where sutures are needed for only 5 to 7 days. Interrupted sutures are placed in the skin. A strip of skin closure tape *(see page 79)* is placed lengthwise over the incision. When the tape is removed in 5 to 7 days, the underlying sutures are sufficiently digested so that the knots and suture on the outside of the skin lift off with the tape. This fast absorbing surgical gut has less tensile strength than plain surgical gut of comparable U.S.P. size. *This material is not to be used internally.*

Chromic gut is treated in a chromium salt solution which conditions it to resist body enzymes, thus prolonging absorption time over 90 days. The chromicizing process, TRU-CHROMICIZING, bathes each ribbon before spinning into strands. The collagen pure ribbons are immersed into a buffered chrome tanning solution. The concentration of chromium salt and the duration of the TRU-CHROMICIZING process are precisely controlled to distribute the chromium uniformly throughout each ribbon. After spinning, the entire cross section of the strand is evenly chromicized. This treatment alters the color of the surgical gut from the

*Trademark

yellowish-tan shade of plain gut to a shade of brown.

Chromic gut is used, at the surgeon's discretion, in tissues which heal relatively slowly and need support for a longer period of time than provided by plain gut, i.e., fascia and peritoneum. It is less irritating and causes less tissue reaction than does plain gut during the early stages of wound healing, but both types produce a moderate tissue reaction that incites wound healing. Tensile strength of chromic gut is retained for 10 to 14 days, with some measurable strength up to 21 days.

COLLAGEN SUTURE. Collagen sutures are extruded from a homogeneous dispersion of pure collagen fibrils from the flexor tendons of beef. Both the plain and chromic types of collagen are similar in appearance to surgical gut. However, by a chemical treatment to remove noncollagenous materials, the tendons are purified and processed into strands which have physical properties superior to surgical gut. Whereas surgical gut is affected by individual variations that exist from animal to animal, collagen sutures are processed from a homogeneous mass. This pure protein material has inherent plastic deformity that causes the material to flatten out at the knot. This is a benefit in ophthalmic surgery, where these sutures are primarily used. Collagen sutures produce minimal tissue reaction, have uniformity of absorption within 56 days, and good knot-holding ability up to ten days. After ten days only about ten percent of tensile strength is left.

**Synthetic Absorbables**

VICRYL* *(polyglactin 910)* SUTURE. A synthetic absorable suture, polyglactin 910 is a copolymer of lactide *(from lactic acid)* and glycolide *(from glycolic acid)*. Both of these acids exist naturally in the body as part of the metabolic process. The "water repelling" quality of lactide slows down the penetration of water into the filaments of the suture, and thus slows the rate of *in vivo* tensile strength loss as compared to sutures absorbed by enzymatic digestion. The bulky lactide groups also help keep the submicroscopic polymer chains comprising the filaments spaced apart so that absorption of the suture mass, after strength is lost, is rapid. The precisely controlled combination of these two substances results in a molecular structure which maintains sufficient tensile strength for efficient approximation of tissues during the critical wound healing period, and then rapidly absorbs.

*Trademark

Approximately 60 percent of its original tensile strength remains at 14 days, while at 21 days 30 percent of its original strength is retained. Absorption is minimal until about the 40th day. Absorption is essentially complete between 60 and 90 days. Synthetic absorbable sutures are absorbed by a slow hydrolysis in the presence of tissue fluids. Enzymes are not required to break down the polymer chains; only water is required. Thus synthetic absorbable sutures exhibit a lower degree of tissue reaction than surgical gut. After implantation, water gradually penetrates the filaments of the suture and the polymer chain begins to break down.

The copolymer is extruded into monofilament strands. VICRYL monofilament sutures, dyed violet to enhance visibility in tissue, are available for use in ophthalmic surgery. Conjunctival sutures remaining in place longer than seven days may cause localized irritation and should be removed as indicated.

Individual monofilament strands, either dyed violet or undyed *(natural)*, also are braided into suture strands and coated. *(Descriptions follow.)*

COATED VICRYL* *(polyglactin 910)* SUTURE. Prepared by coating VICRYL braided suture material, Coated VICRYL sutures fill the need for a smoother synthetic absorbable product that will pass through tissue readily with minimal drag. The coating is a mixture composed of equal parts of a copolymer of glycolide and lactide *(polyglactin 370)* and calcium stearate. Calcium stearate is a compound that is used extensively in pharmaceutical preparations and foods. It is a salt of calcium and stearic acid. Both are present in the body and are constantly being metabolized and excreted.

The mixture of polyglactin 370 and calcium stearate combines the excellent properties of each to produce an outstanding absorbable, adherent, nonflaking lubricant. The lubricating property of the coating leads to smooth passage through tissue, precise knot placement and smooth tie down.

Like the suture itself, this coating absorbs rapidly and predictably within 90 days. These sutures are inert, nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption. At two weeks post-implantation approximately 60 percent of the original tensile strength remains, while at three weeks approximately 30 percent of the original strength is retained. Absorption of these sutures is minimal until about the 40th post-implantation day. Absorption is essentially complete between the 60th and 90th days. The acids of

the constituent monomers *(lactide and glycolide)* are readily eliminated from the body, primarily in the urine.

The safety and effectiveness of Coated VICRYL sutures in neural tissue and in cardiovascular tissue have not been established. Skin and conjunctival sutures remaining in place longer than seven days may cause localized irritation and should be removed as indicated. Coated VICRYL sutures may be used in the presence of infection because of the monofilament-like construction.

Coated VICRYL sutures are available as braided dyed violet and undyed (*natural*) strands in a variety of lengths, with or without needles.

PDS* *(polydioxanone)* SUTURE. A monofilament synthetic absorbable suture, PDS suture is prepared from the polyester poly *(p-dioxanone)*. This suture material is particularly useful where the combination of an absorbable suture and extended wound support up to six weeks is desirable. Approximately 70 percent of its original strength remains two weeks after implantation. At four weeks post-implantation, approximately 50 percent of its original strength is retained, and at six weeks, approximately 25 percent of the original strength is retained. PDS suture provides wound support twice as long as other synthetic absorbable sutures.

Absorption is minimal until about the 90th postoperative day. Absorption is essentially complete within six months. Only a slight tissue reaction is provoked during this period. PDS suture is absorbed *in vivo* through a simple hydrolytic mechanism.

The polymer contains an oxygen ether group. It is this component which enables soft, pliable monofilament construction. It may be used in the presence of infection. The safety and effectiveness of PDS sutures in neural tissue and cardiovascular tissue have not been established. For other tissues, nonantigenic, nonpyrogenic PDS sutures are available clear or dyed violet to enhance visibility in tissues.

## NONABSORBABLE SUTURES

By U.S.P. definition, "nonabsorbable sutures are strands of material that are suitably resistant to the action of living mammalian tissue. A suture may be composed of a single or multiple filaments of metal or organic fibers rendered into a strand by spinning, twisting or braiding. Each strand is substantially uniform in diameter throughout its length within U.S.P. limitations for each size. The material may be uncolored, naturally colored, or dyed with an F.D.A. approved dyestuff. It may be coated or uncoated; treated or untreated for capillarity."[4] Capillarity refers to the characteristic that allows the passage of tissue fluids along the strand permitting infection, if present, to be drawn along the suture line.

The U.S.P. classifies and types nonabsorbable surgical sutures as follows: Class I suture is composed of silk or synthetic fibers of monofilament, twisted or braided construction. Class II suture is composed of cotton or linen fibers or coated natural or synthetic fibers where the coating forms a casing of significant thickness but does not contribute appreciably to strength. Class III suture is composed of monofilament or multifilament metal wire. *Fig. 9* lists the nonabsorbable suture materials and gives the basic raw material from which each is manufactured.

Basically, nonabsorbable sutures are those which are not absorbed or digested by body enzymes or do not hydrolyze in body tissues. For this reason, nonabsorbable sutures are removed postoperatively when placed in exposed tissues such as the skin or the eye. When buried in body tissues, they become encapsulated or permanently surrounded by tissue.

**Fig. 9 Nonabsorbable sutures: Basic raw materials**

| Suture | Raw Material |
|---|---|
| Surgical Silk | Raw silk spun by silkworm |
| Dermal | Silk with tanned protein coating |
| Virgin Silk | Natural silk filaments |
| Surgical Cotton | Long staple cotton fibers |
| Linen | Long staple flax fibers |
| Stainless Steel Wire | Specially formulated iron-nickel-chromium alloy |
| Synthetics: Nylon † | Polyamide polymer |
| Polyester Fiber ‡ Uncoated Coated | Polymer of polyethylene terephthalate may be coated |
| Polypropylene § | Polymer of propylene |

‡ETHIBOND* Polyester Suture
‡ETHIFLEX* Polyester Fiber Suture
†ETHILON* Nylon Suture
‡MERSILENE* Polyester Fiber Suture
†NUROLON* Braided Nylon Suture
§PROLENE* Polyprolene Suture
*Trademarks of ETHICON, INC.

4. Ibid
*Trademark

## Natural Nonabsorbables

SURGICAL SILK. The most widely used nonabsorbable suture material is surgical silk. The dominant role of silk is attributable to its long-standing use and to the fact that for many surgeons it represents the standard of performance, particularly in handling properties, by which newer synthetic materials are judged. Silk filaments can be twisted or braided together to form the suture strand. The braided type is preferred by most surgeons because of its superior handling qualities.

The raw material is a continuous filament spun by the silkworm larva in making its cocoon. Raw silk is graded according to such factors as strength, uniformity of filament diameter, and freedom from defects. Careful selection and use of only the top grades of silk filaments are significant factors in the manufacture and performance of PERMA-HAND* silk suture. The filaments from several cocoons are combined in various arrangements to produce the variety of threads needed to braid the full range of suture sizes.

Cream or orange colored in its raw state, each filament is processed to remove the natural waxes and gums. When the silkworm spins its cocoon, it extrudes not only the silk filament but also a gum, sericin, which holds the cocoon together. This gum offers no benefit to the quality of braided silk sutures, so it is removed. In the ETHICON process for most suture sizes, this degumming operation is carried out before braiding. This allows for tighter and more compact braiding and significantly improved finished suture quality. Following the degumming and braiding processes, the strands are dyed with logwood dye, scoured and stretched, and then impregnated and coated with a special mixture of waxes. Each of these steps is critical to the quality of the finished suture, as is the order in which the steps are carried out.

Untreated silk has a capillary action. Therefore, surgical silk is treated to reduce this capillarity. It also is dyed, most commonly black, for easy visibility in tissues. Because it loses tensile strength when exposed to moisture, it is used dry.

Although silk is classed by the U.S.P. as a nonabsorbable suture, long-term studies of this material *in vivo* show that it will have lost most or all of its tensile strength in about one year and usually cannot be found after two years. Thus it behaves in reality as a very slowly absorbable suture.

VIRGIN SILK. Virgin silk suture consists of several natural silk filaments drawn together and twisted to form a fragile strand of very small diameter *(8-0 and 9-0)* for use in ophthalmic surgery. The sericin gum is not removed and serves to hold the silk filaments together.

Although it requires extra careful handling, virgin silk enables the surgeon to place very fine sutures close together for excellent tissue approximation of delicate structures with extremely small knots. The surgeon may choose to use a "temporary dye" to enhance suture visibility if white virgin silk is used rather than black. In this case, a small amount of methylene blue is sometimes dropped inside the foil packet by a member of the surgical team before the strand is removed.

SURGICAL COTTON. Cotton is a natural cellulose fiber. Surgical cotton suture is made from individual long staple Egyptian cotton fibers that are combed, aligned and twisted into a strand. Before the cotton strand is ready for suture use, it must undergo several chemical purification processes. The natural cotton fiber, in addition to cellulose, contains natural impurities that include waxes, pectins *(gums)*, nitrogenous substances *(vegetable protein matter)*, pigments and foreign wind-blown mineral matter *(sand)*. A scouring operation, using mild detergents and dilute solutions of alkali, removes the waxes, pectinaceous and extraneous matters. A final bleaching operation produces a white thread. The strand is coated to produce a smooth surface over the staple fibers.

The weakest of the commonly used nonabsorbable materials, cotton does gain tensile strength when wet. Therefore, it is moistened prior to use. Like silk, cotton suture may be selected for use in most body tissues. Implanted in tissue, cotton loses 50 percent of its strength in six months, but still has 30 to 40 percent of its strength at the end of two years.

LINEN. Made from twisted long staple flax fibers, linen suture is occasionally used in gastrointestinal surgery. The diameter of linen strands cannot be accurately controlled and tensile strength is inferior to other nonabsorbable materials.

SURGICAL STAINLESS STEEL. For surgical stainless steel sutures, the absence of toxic elements, flexibility and fine wire size are essential criteria. The 316L *(L for low carbon)* steel alloy formula used in the manufacture of surgical stain-

*Trademark

less steel wire sutures represents optimum metal strength, flexibility, uniformity and compatibility with stainless steel implants and prostheses. It should not be used when a prosthesis of another alloy is being implanted due to possibility of an unfavorable electrolytic reaction.

Both monofilament and twisted multifilament stainless steel sutures have high tensile strength and low tissue reactivity due to inertness. "Steel wire lasts indefinitely but may corrode and break at points of bending, twisting or knotting."[5] Steel is used in abdominal wall closure, sternal closure, retention and skin closure, tendon repair and certain other orthopaedic procedures, and in neurosurgery.

"Some surgeons dislike wire because of the difficulties in handling it. Wire does hold a knot well. It is strong and as long as it does not fragment, there is little loss of strength in tissues. As claimed by its proponents, wire causes very little tissue reaction, although our studies suggest some cutting action. The disadvantages are the handling, the fragmentation, and, if used for fascial closure in a thin patient, the presence of an easily palpable suture that occasionally pushes out through the skin."[6]

Occasionally difficulties also may be encountered in the manual technic of using stainless steel sutures for bone approximation and fixation. "Asymmetric twisting of the wire leads to potential wire buckling, metal fatigue and subsequent wire fracture. Incomplete wire fixation under these circumstances will result in motion between the approximated sides of the sternum, resulting in postoperative pain and possible dehiscence."[7]

Kinks in the strand can make steel sutures practically useless. Steel can pull or tear tissue if tied too tightly. Barbs on the strand can tear gloves, thus breaking sterile technic, or traumatize tissue. For this reason, packaging has played a unique part in the development of surgical steel products.

Many surgeons refer to wire size by the Brown and Sharpe (B & S) gauge of 40, the smallest diameter, to 18, the largest. Suture manufacturers label surgical stainless steel with both the B & S gauge and U.S.P. diameter size classifications. *(Refer to Fig. 10 Surgical stainless steel: wire gauge equivalents.)*

**Fig. 10 Surgical stainless steel: wire gauge equivalents**

| Diameter | U.S.P. | B & S |
|---|---|---|
| .0031 inch | 6-0 | 40 |
| .0040 | 6-0 | 38 |
| .0056 | 5-0 | 35 |
| .0063 | 4-0 | 34 |
| .0080 | 4-0 | 32 |
| .0100 | 3-0 | 30 |
| .0126 | 2-0 | 28 |
| .0159 | 0 | 26 |
| .0179 | 1 | 25 |
| .0201 | 2 | 24 |
| .0226 | 3 | 23 |
| .0254 | 4 | 22 |
| .0320 | 5 | 20 |
| .0354 | 6 | 19 |
| .0403 | 7 | 18 |

## Synthetic Nonabsorbables

ETHILON* NYLON SUTURE. A polyamide polymer derived by chemical synthesis, nylon is extruded into a noncapillary single or monofilament strand. It has high tensile strength and tissue reaction is extremely low. It degrades *in vivo* at a rate of about 15 to 20 percent per year by hydrolysis.

ETHILON sutures in sizes 6-0 and larger are produced from a special grade known as nylon 6. This is intrinsically stronger than nylon 6-6, the medical grade polyamide used for sizes 7-0 and finer. Pliability characteristics of both these materials permit good handling. However, these monofilament sutures have a tendency to attempt to return to their original straight extruded state, a property commonly known as "memory." More throws in the knot are required to securely hold monofilament than braided nylon. Monofilament nylon in a wet or damp state is more pliable and easier to handle than dry nylon. A limited line of ETHILON sutures, sizes 3-0 through 6-0, for cosmetic plastic surgery are pliabilized in the manufacturing process. This moisturized state provides handling and knot tying characteristics similar to braided sutures.

Because of its elasticity, nylon is particularly well suited for retention and skin closure. It is available clear or dyed green or black for better visibility. ETHILON sutures are also frequently used in ophthalmology and microsurgery in very fine sizes. Sizes 9-0 and 10-0 have an intensified black dye for high visibility.

5. Clark DE: Surgical suture materials, *Contemporary Surg 17:*43, July 1980
6. Sabiston DC Jr (ed): *Davis-Christoper Textbook of Surgery: The Biological Basis of Modern Surgical Practice*, 11th ed, Philadelphia: Saunders, 1977, p. 332
7. Cohn JD, Valente dos Santos M: Sternal wire closure by an instrumental method, *Am J Surg 132:*668, Nov 1976

*Trademark

NUROLON* BRAIDED NYLON SUTURE. Composed of filaments of nylon that have been tightly braided into a multifilament strand, NUROLON suture is treated for noncapillarity. Available white or dyed black, it looks, feels and handles similarly to silk, but is stronger and elicits less tissue reaction. Braided nylon can be used in all tissues where a multifilament nonabsorbable suture is acceptable. It is generally recognized that braided nylon sutures lose 15 to 20 percent of their tensile strength per year in tissue.

MERSILENE* POLYESTER FIBER SUTURE. Untreated fibers of polyester *(polyethylene terephthalate)* are closely braided into a multifilament strand. Polyester fiber suture is stronger than natural fibers and causes minimal tissue reaction. Available white or dyed green, it is not weakened by wetting prior to use. It does have a higher coefficient of friction when passed through tissue because the suture is untreated with regard to a coating.

Polyester fiber is one of the most acceptable materials for vascular synthetic prostheses. Many surgeons use MERSILENE suture, or a coated polyester suture, for suturing these in place. MERSILENE suture was the first synthetic braided suture material that was shown to last indefinitely in the body.

ETHIBOND* POLYESTER SUTURE. This suture is a braided strand of polyester (*polyethylene terephthalate*) fibers uniformly coated with polybutilate. The highly adherent coating is a biologically inert nonabsorbable compound. It acts as a lubricant to mechanically improve the physical properties of the uncoated suture by improving ease of passage through tissues and by providing excellent pliability and handling qualities as contrasted to the braided uncoated fiber. Polybutilate was the first coating developed specifically as a surgical suture lubricant. It is a polyester material which adheres strongly to the braided polyester fiber strand.

Both the polyester fiber suture material and the polybutilate coating are pharmacologically inactive. The prolonged retention strength *in vivo* typical of polyester sutures has been shown to be unaffected by the coating. ETHIBOND sutures are inert and elicit minimal tissue reaction. They are braided for optimal handling properties, and are available white or dyed green for good visibility in the surgical field. Polyester fiber coated with polybutilate provides smooth passage through tissue and smooth tie-down on each throw of the knot. It is used primarily in cardiovascular surgery for vessel anastomosis and placement of prosthetic materials because it retains its strength *in vivo* for extended periods.

ETHIBOND sutures, green and white, are also available attached to TEFLON† felt pledgets. These pledgets are used as a buttress under sutures when there is a possibility of adjacent friable tissue tearing. Pledgets are most commonly used in heart valve replacement procedures to prevent the annulus from tearing when the prosthetic valve is seated and the sutures are tied. Some surgeons use pledgets routinely in valve surgery. Others use them in situations in which extreme deformity, distortion or tissue destruction at the annulus is encountered.

PROLENE* POLYPROPYLENE SUTURE. Polypropylene is an isotactic crystalline stereoisomer of a linear hydrocarbon polymer containing little or no unsaturation. It is manufactured by a patented process to enhance pliability and handling. It may be clear or pigmented blue. The suture is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

Extremely inert in tissue, polypropylene retains its high tensile strength in tissue, causes minimal tissue reaction and holds knots better than most other synthetic monofilament materials. Because of its lack of adherence to tissue, PROLENE suture is efficacious as a pull-out suture.

Polypropylene has gained wide acceptance in general, cardiovascular, plastic and orthopaedic surgery. Due to its relative biological inertness, it is recommended for use where the least possible suture reaction is desired. As a true monofilament, PROLENE suture resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion.

## MONOFILAMENT AND MULTIFILAMENT SUTURES

PDS *(polydioxanone)* suture, plain and chromic surgical gut and collagen sutures are monofilament absorbable sutures. Although the larger sizes of surgical gut are made from two or more coalesced

*Trademark

†Trademark of E.I. DuPont de Nemours & Co. for TFE Fluorocarbon

ribbons of sheep submucosa or beef serosa, the finished strand behaves as a noncapillary monofilament suture. Monofilament nonabsorbable sutures include surgical stainless steel, ETHILON nylon suture and PROLENE polypropylene suture. Most surgeons choose monofilament sutures in the presence of infection. However, acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

Multifilament sutures are either braided or twisted. Although Coated VICRYL *(polyglactin 910)* sutures, dermal and ETHIBOND polyester sutures are coated to enhance their handling characteristics, they retain their multifilament character. With the exception of VICRYL sutures, the multifilament sutures are nonabsorbable. These include silk, cotton, twisted multifilament stainless steel, NUROLON braided nylon and polyester fiber sutures.

Because of their construction, monofilament sutures are more susceptible to damage during handling than multifilament sutures. Crushing or crimping can knick or create a weak spot in the strand that may result in suture breakage. The postoperative evaluation of Roy, et al, of suture remnants indicates that a common form of damage may have been initiated by contact with an instrument followed by sharp bending of the fiber.[8] Thus "extreme care must be taken to avoid trauma to monofilament suture."[9]

## SUMMARY OF SUTURE MATERIALS

Table I lists the suture materials most commonly used in surgery, their characteristics, how supplied, uses and contraindications.

## KNOT SECURITY AND KNOT TYING

The construction of ETHICON* sutures has been carefully designed to produce the optimum combination of strength, uniformity and hand for each material. The term *hand* is the most subtle of all suture quality aspects. It relates to the feel of the suture in the surgeon's hands, the smoothness with which it passes through tissue and ties down, the way in which knots can be set and snugged down, and most of all, to the firmness or body of the suture. *Extensibility* relates to the way in which the suture will stretch slightly during knot tying and then recover. The stretching characteristics provide the signal that alerts the surgeon to the precise moment when the suture knot is snug. Multifilament sutures are generally easier to handle and to tie than monofilament sutures, however, all the synthetic materials require a specific knotting technic *(see Fig. 11)*.

Monofilament synthetic polymeric materials possess the property of memory. *Memory* is the built-in orientation of the polymer produced by stretching or drawing during the extrusion of the filament. In other words, the coefficient of friction in monofilament sutures is relatively low. Monofilament nylon in larger sizes has the greatest proclivity for knot slippage. Most surgeons have had the experience of discovering that a carefully tied knot in monofilament nylon may eventually loosen. This is relatively unimportant in skin sutures, but many surgeons tie one knot for each day they wish the suture to remain in place.

When knot security is critically important, as in the placement of an artificial heart valve for example, synthetic multifilament sutures, usually polyesters, are normally used. Additional knots are usually tied to maximize knot security.

**Fig. 11 Knot tying technics:**

| Suture Material | Knot Tying |
|---|---|
| Surgical Gut<br>Collagen<br>Surgical Silk<br>Dermal<br>Virgin Silk<br>Surgical Cotton<br>Surgical Stainless Steel | Square knot technic |
| Uncoated Synthetics †<br>Polyester Fiber<br>Polyglactin 910 | Place the first throw in a precise position for the final knot, using a double loop. Tie second throw square, using horizontal tension. Additional throws are advisable. |
| Coated Synthetics ‡<br>Polyester Fiber<br>Polyglactin 910<br>Monofilament<br>Synthetics §<br>Polydioxanone<br>Polypropylene<br>Nylon | Standard technic of flat and square ties with additional throws if indicated by surgical circumstances and the experience of the surgeon. |

‡Coated VICRYL* (polyglactin 910) Suture
‡ETHIBOND* Polyester Suture
†MERSILENE* Polyester Fiber Suture
§PDS* (polydioxanone) Suture
§PROLENE* Polypropylene Suture
†VICRYL* (polyglactin 910) Suture
*Trademarks of ETHICON, INC.

8. Roy J et al: Cardiovascular sutures as assessed by scanning electron microscopy, *Scanning Electron Microscopy 3:* 204, 1980
9. Reul GJ: The role of sutures in complications in vascular surgery and their relationship to pseudoaneurysm formation, *Complications in Vascular Surgery,* New York, Grune & Stratton, 1980, 631

*Trademark

**Table I**
**Suture Materials Commonly Used in Surgery**

| SUTURE | TYPES | COLOR OF MATERIAL | RAW MATERIAL | TENSILE STRENGTH RETENTION *in vivo* | ABSORPTION RATE |
|---|---|---|---|---|---|
| Surgical Gut | Plain | Yellowish-tan<br>Blue Dyed | Collagen derived from healthy mammals. | Lost within 7–10 days. Individual patient characteristics can affect rate of tensile strength loss. | Digested by body enzymes within 70 days. |
| Surgical Gut | Chromic | Brown<br>Blue Dyed | Collagen derived from healthy mammals. Treated to resist digestion by body tissues. | Lost within 21–28 days. Individual patient characteristics can affect rate of tensile strength loss. | Digested by body enzymes within 90 days. |
| †Coated VICRYL (Polyglactin 910) | Braided | Violet<br>Undyed (Natural) | Copolymer of lactide and glycolide coated with polyglactin 370 and calcium stearate. | Approximately 60% remains at two weeks. Approximately 30% remains at three weeks. | Minimal until about 40th day. Essentially complete between 60–90 days. Absorbed by slow hydrolysis. |
| †PDS (polydioxanone) | Monofilament | Violet<br>Clear | Polyester polymer | Approximately 70% remains at two weeks. Approximately 50% remains at four weeks. Approximately 25% remains at six weeks. | Minimal until about 90th day. Essentially complete within 210 days. Absorbed by slow hydrolysis. |
| Surgical Silk | Braided | Black<br>White | Natural protein fiber of raw silk spun by silkworm. | Loses most or all in about one year. | Usually cannot be found after two years. |
| Surgical Cotton | Twisted | White<br>Blue<br>Pink | Natural long staple cotton fibers. | Loses 50% in six months. Has 30–40% at end of two years. | Nonabsorbable: remains encapsulated in body tissues. |
| Surgical Steel | Monofilament<br>Multifilament | Silver metallic | An alloy of iron-nickel-chromium. | Indefinite | Nonabsorbable: remains encapsulated in body tissues. |
| ETHILON Nylon | Monofilament | Black<br>Green<br>Clear | Polyamide polymer | Loses 15–20% per year. | Degrades at a rate of about 15–20% per year. |
| NUROLON Nylon | Braided | Black<br>White | Polyamide polymer | Loses 15–20% per year. | Degrades at a rate of about 15–20% per year. |
| MERSILENE Polyester Fiber | Braided | Green<br>White | Polyester polyethylene terephthalate | Indefinite | Nonabsorbable: remains encapsulated in body tissues. |
| †ETHIBOND Polyester Fiber | Braided | Green<br>White | Polyester polyethylene terephthalate coated with polybutilate | Indefinite | Nonabsorbable: remains encapsulated in body tissues. |
| †PROLENE Polypropylene | Monofilament | Clear<br>Blue | Polymer of propylene | Indefinite | Nonabsorbable: remains encapsulated in body tissues. |

†See package insert for complete product information (*pages 98-100*).

| TISSUE REACTION | CONTRA-INDICATIONS | WARNINGS | FREQUENT USES | HOW SUPPLIED | COLOR CODE OF PACKETS |
|---|---|---|---|---|---|
| Moderate | Should not be used in tissues that heal slowly and require support. | Absorbs relatively quickly. | Ligate superficial vessels; suture subcutaneous and other tissues that heal rapidly; sometimes used in presence of infection, as opposed to a braided nonabsorbable suture.<br>Ophthalmology | 6-0 thru 4-0 with ATRALOC* needles.<br>5-0 thru 3 w/o needles<br>5-0 and 6-0 w/needles | Yellow |
| Moderate, but less than plain surgical gut | Being absorbable, should not be used where prolonged approximation of tissues under stress is required. | Protein-based absorbable sutures have a tendency to fray when tied. | One of the most versatile of all materials; may be used in presence of infection; used in tissues that heal relatively slowly but intended for use as absorbable suture or ligature.<br>Ophthalmology | 7-0 thru 1 with needles<br>5-0 thru 3 w/o needles<br>6-0 and 7-0 w/needles | Beige |
| Mild | Being absorbable, should not be used where prolonged approximation of tissues under stress is required. | Safety and effectiveness in neural and cardiovascular tissue have not been established. | Ligate or suture tissues where an absorbable suture is desirable except where approximation under stress is required. | 8-0 thru 3 with needles<br>5-0 thru 1 w/o needles<br>8-0 thru 1 with needles | Violet |
| Slight | Being absorbable, should not be used where prolonged approximation of tissues under stress is required. | Safety and effectiveness in neural and cardiovascular tissue have not been established. | Abdominal and thoracic closure, subcutaneous tissue, colon and rectal surgery; can use in presence of infection.<br>Orthopaedic, plastic | 9-0 thru 2 with needles<br>7-0 thru 1 with needles | Silver |
| Moderate | Should not be used for placement of vascular prostheses and artificial heart valves. | Slowly absorbs. | Most body tissues for ligating and suturing. General surgery, ophthalmology and plastic surgery. | 9-0 thru 2 with needles<br>4-0 thru 5 w/o needles<br>5-0 and 4-0 w/needles | Light Blue |
| Minimal | None | None | Most body tissues for ligating and suturing. | 5-0 thru 1 with and w/o needles<br>5-0 thru 3-0 with straight needles<br>5-0 thru 2-0 w/o needles<br>4-0 thru 2-0 w/o needles | Pink |
| Low | Should not be used when a prosthesis of another alloy is implanted. | May corrode and break at points of bending, twisting or knotting. | Abdominal wall and skin closure; sternal closure; retention; tendon repair, orthopaedic and neurosurgery. | 6-0 thru 6 with needles<br>6-0 thru 7 w/o needles<br>5-0 thru 2-0 w/needles<br>4-0 thru 0 w/o needles | Yellow-Ochre |
| Extremely low | None | None | Skin closure; retention; plastic surgery, ophthalmology and microsurgery. | 11-0 thru 2 with needles<br>4-0 thru 2 w/o needles<br>6-0 thru 4-0 with needles<br>6-0 thru 4-0 with needles | Mint green |
| Extremely low | None | None | Most body tissues for ligating and suturing. General closure; neurosurgery. | 7-0 thru 1 with needles<br>4-0 thru 0 w/o needles<br>6-0 thru 4-0 with needles | Mint green |
| Minimal | None | None | Cardiovascular, general and plastic surgery; retention; ophthalmology. | 10-0 thru 5 with needles<br>5-0 thru 0 w/o needles<br>6-0 thru 2-0 with needles<br>5-0 thru 2-0 w/o needles | Turquoise |
| Minimal | None | Has not been evaluated in ophthalmic surgery. | General surgery, cardiovascular and plastic surgery; retention. | 7-0 thru 5 with needles<br>5-0 thru 0 w/o needles<br>5-0 thru 0 w/needles | Orange |
| Minimal transient acute inflammatory reaction | None | None | General, plastic, cardiovascular surgery and skin closure; ophthalmology. | 6-0 thru 4-0 with needles<br>10-0 thru 2 w/needles | Deep Blue |

*Trademark

With multifilament sutures, particularly Coated VICRYL suture, silk and cotton, the knots do not tend to slip. The nature of the material and the braided or twisted construction provide a high coefficient of friction and the knots remain as they were laid down.

Suture knots must be properly placed to be secure. Most surgeons are taught to tie square or surgeon's knots. These are appropriate for tying the natural materials. However, when knots are examined after they have been in place for some time, they frequently appear as a series of half-hitches. Speed in tying knots frequently results in less than perfect placement of the strands. In Herrmann's study, "knot security proved to be a much more variable characteristic than breaking strength. In addition to variables inherent in the material itself, considerable variation was found between knots tied by different individuals and even between knots tied by the same individual on different occasions."[10]

Knot security for the synthetic materials requires the standard technic of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the surgeon. Polypropylene, for example, exhibits a small degree of plasticity. If polypropylene is tied carefully and the knots set firmly, a flattening occurs where the strands cross. This helps lock the knot. The key to the proper use of these materials is meticulous technic in laying flat knots and setting each knot as it is tied. *Fig. 11* lists the appropriate knot tying technics for each material.

10. Herrmann JB: Tensile strength and knot security of surgical suture materials, *Am Surg 37:* 211, April 1971

SECTION IV

# Suture Selection

## SUTURE PREFERENCE

Surgical speciality may be a factor in the surgeon's choice of suture material. For example, in OB-Gyn procedures, surgical gut frequently is the preferred material for all tissue layers except skin. As a group, orthopaedic surgeons use Coated VICRYL* *(polyglactin 910)* suture and stainless steel suture predominantly. Many plastic surgeons prefer synthetic materials characterized by their minimal tissue reaction. The majority of neurosurgeons prefer surgical silk or NUROLON* braided nylon suture. It should be clearly understood, however, that individual surgeon preferences exist within each speciality. No single suture material is used exclusively by every surgeon who practices in a specific speciality. The surgeon's choice is influenced by many factors, including personal experience, basic knowledge of healing characteristics of various tissues and organs, and the physical and biological characteristics of suture materials. Finally, surgeons continue using suturing technics and suture preferences learned in the institutions where they trained.

## SUTURE NEEDS IN ABDOMINAL SURGERY

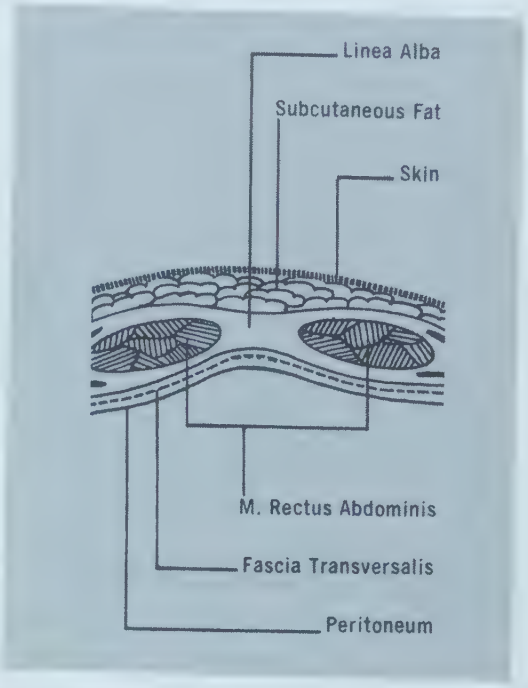
### Sutures Needed "Going In"

Unless the surgeon prefers to seal subcutaneous blood vessels with an electrosurgical unit, free ties *(ligatures)* will be needed almost immediately after the incision is made. An absorbable suture material is generally preferred. When preparing the ties, the experienced scrub nurse often prepares one strand on a needle for use as a suture ligature. Blood vessels are frequently encountered at the tendinous insertions of the rectus muscle. The surgeon may wish to transfix a large blood vessel.

### Sutures Needed "Inside"

Sutures required inside the peritoneal *(abdominal)* cavity will depend on the nature of the operation and the surgeon's technic.

Fig. 12 Layers of abdominal wall




### *Sutures for Gastrointestinal Tract*

The principle problem in closing wounds of the gastrointestinal tract is leakage. Any leakage from an anastomosis or suture site can cause localized or generalized peritonitis. A leak-proof anastomosis can be achieved with either a single or double layer closure. For a single layer closure, interrupted nonabsorbable sutures may be placed approximately ¼ inch *(6 mm)* apart through the submucosa, into the muscularis and through the serosa. PROLENE* polypropylene suture is used frequently for this type of closure.

The submucosa provides strength in the gastrointestinal tract, therefore, good closure involves suturing the submucosal layers in apposition. "Repair of this layer is usually accomplished with interrupted nonabsorbable sutures that do not penetrate the mucosa."[1] "With the available methods of decompression of the gastrointestinal tract, great strength of suture material should not be needed. Thus a continuous absorbable suture, not cinched up tightly, placed in the submucosa usually suffices for anastomosis."[2] A continuous suture technic provides a tighter seal than interrupted sutures. However, if a continuous suture breaks, the entire suture line may separate. Many surgeons, therefore, prefer to place a second layer of sutures through the serosa, for insurance. Usually silk or other nonabsorbable suture is utilized employing an interrupted technic.

Sutures should not be tied too tightly in performing anastomotic closure. Wounds of the stomach and intestine, because of their rich blood supply, be-

1. Hunt TK, Dunphy JE (ed): *Fundamentals of Wound Management*, New York: Appleton-Century-Crofts, 1979, p. 436
2. VanWinkle W, Salthouse TN: *Biological Response to Sutures* and *Principles of Suture Selection*, Somerville, NJ: ETHICON Research Foundation, 1976, p. 13

*Trademark

come very edematous and eventually indurated. Tight sutures may cut through the tissue and provide channels for leakage.

Inverting, everting or end-to-end closure technics are used. All have been employed successfully, and all have some drawbacks. Perhaps the most important aspect is to exercise meticulous care in placing the sutures and trying to use the submucosa as the layer to be sutured. Even with the best technics some leakage may occur. Fortunately, the omentum usually confines the area and natural body defenses handle the problem.

STOMACH. Surprisingly, for an organ that contains free hydrochloric acid and potent proteolytic enzymes, the stomach heals rapidly, attaining maximum strength within 14 to 21 days postoperatively. Stomach wounds have a peak rate of collagen synthesis at five days. Absorbable sutures are usually acceptable in the stomach, although they may produce a moderate reaction in both the wound and normal tissue. PROLENE suture is probably the most innocuous suture material. Silk produces the greatest cellular reaction in the stomach.

SMALL INTESTINE. Closure of the small intestine presents many of the same problems as the stomach. Leakage of distal small intestinal contents is usually not a serious problem. Proximal intestinal contents may be largely bile or pancreatic juice and cause a severe chemical peritonitis, rather than bacterial. However, if an inverting technic of closure is used, care must be taken to keep the cuff of tissue which protrudes into the lumen as small as possible in order to avoid partial or complete obstruction of the small sized intestinal lumen. Absorbable sutures are usually preferred, particularly since they will not provide a permanent limit on lumen diameter. The small intestine heals very rapidly and maximal strength is reached in about 14 days. A nonabsorbable suture sometimes is used in the serosal layer for added assurance.

COLON. The colon behaves like the stomach and small intestine insofar as the rate of healing is concerned. However, a high rate of collagen synthesis is maintained for a prolonged period *(over 120 days)* despite formation of only a thin fibrous scar. The entire gastrointestinal tract shows a loss of collagen and increased collagenous activity immediately after colon anastomosis.

The high microbial content is a potential contaminating factor in wounds of the large intestine. Although enemas and antibiotics used in preoperative bowel preparation reduce the level of bacterial contamination, they do not eliminate it. Leakage of large bowel contents is potentially more serious than in other areas of the gastrointestinal tract. Absorbable sutures, when absorbed, leave no channel for microbial migration. Although this may be an advantage in colon surgery, single layer leakproof anastomoses also may be performed using monofilament nonabsorbable sutures. Avoidance of mucosal penetration and placement of sutures in the submucosa are technical maneuvers that will aid in avoiding complications.

The colon has a marked strength gradient, being about twice as strong in the sigmoid region as in the cecum. Wounds of the colon gain strength at the same rate regardless of location. Thus, the same size suture may be used at either end of the colon. Coated VICRYL *(polyglactin 910)* suture would appear to be ideally suited because of its reliable rate of absorption after 28 days, if an absorbable suture is preferred.

RECTUM. The rectum is notoriously slow to heal. Because the lower portion is below the pelvic peritoneum, it does not have serosa. A large bite of muscle should be included in an anastomosis, and the sutures are tied carefully to avoid cutting through the tissues. Monofilament sutures are indicated because of the potential microbial contamination in the rectum.

### *Sutures for Biliary Tract*

The cystic and common bile ducts heal rapidly. The contents of these ducts present special considerations in relation to suture use. Selection of suture material remains controversial. The presence of a foreign body, such as a suture, in fluids that are nearly saturated with crystalloids may serve to initiate precipitation or crystallization. Thus, sutures in contact with bile in the biliary tract may act as a nidus for stone formation. Multifilament nonabsorbable sutures probably should not be used because it is not always possible to prevent exposure of a suture in the ducts. Therefore, absorbable sutures may be preferred and should always be used in fine sizes that present the least surface area to exposure. Monofilament nonabsorbable suture, particularly PROLENE suture can be used safely.

### *Sutures for Parenchymatous Organs*

On occasion, lacerations of spleen, kidney or liver must be repaired, usually to control hemorrhage or oozing. If large vessels, particularly arteries within the substance of the organ are severed, these must be located and ligated before attempting to close

the laceration. Otherwise hematomas or failure of the repair with secondary hemorrhage will occur. Sutures will not hold well in an organ composed chiefly of cells, with little connective tissue support. Attempts must be made to coapt the outer fibrous capsule of the organ. Only small size sutures need be used since, in the absence of hemorrhage, little tension will be placed on the suture line. If the cut edges of the capsule cannot be approximated, tacking a piece of omentum over the defect will usually suffice to provide closure. Sutures do not need to be placed close together or deeply into the organ. Repair of such defects is usually rapid and a new fibrous capsule will usually cover the defect within one week or ten days. If oozing is a problem, the wound is often packed and drained with no attempt at primary repair.

## Sutures for Closure

The function of sutures is to maintain apposition of the tissues until the healing of the wound renders artificial support unnecessary. This is particularly important in closure of the abdominal wall to prevent wound disruption. "Perhaps of more importance than the type of suture material used is the method of closure."[3] For the layered closure method, the wound is sutured in layers with the sutures placed close to the tissue edges. In selected patients, closure with retention sutures is preferable. These are placed at a distance from the edge of the wound to take advantage of the bulk of the tissues to hold the sutures.

### *Layered Closure*

PERITONEUM. Suture for the peritoneum usually is the first stitch the surgeon needs to close the abdomen. The peritoneum is the thin membranous lining of the abdominal cavity beneath the posterior fascia. Peritoneum heals quickly. It is debatable whether or not the peritoneum needs suturing. If the posterior fascia is securely closed, it is doubtful that suturing the peritoneum contributes anything to the prevention of an incisional hernia. If the peritoneum is closed, continuous technic with an absorbable suture usually is preferred, however interrupted sutures can be used.

FASCIA. Fascia, the layer of firm connective tissue covering muscle, is the major supportive structure of the body. Fascia is the strongest tissue in the abdominal wall and in many other sites in the body. Fascia heals very slowly. It regains approximately 40 percent of its original strength in two months. It takes many months, usually more than one year, for maximum strength to be regained. Full original strength is never regained. Therefore, in closing an abdominal incision, reliance is placed on the fascial sutures to hold the wound closed and to resist changes in intraabdominal pressure.

"Because of the slow healing time and because a fascial suture must bear the maximum stress of the wound, a moderate size nonabsorbable suture should be used."[4] In the absence of infection or gross contamination, either multifilament or monofilament sutures may be used. In the presence of infection or gross contamination, a monofilament absorbable or an inert nonabsorbable, either stainless steel or PROLENE suture, may be used.

Interrupted technic is employed most frequently to close fascia. Care must be taken not to strangulate tissue, thus interfering with blood supply. Sutures must not be tied too tightly, thus encouraging "cutting out" of the suture. Most suture materials, except steel, have some degree of elasticity. A wound becomes swollen and edematous shortly after it is inflicted. The suture, if not tied too tightly, will "give" with the increased bulk of tissue and, as the swelling subsides, will accommodate to the new dimensions. Since it is inelastic, steel sutures tied too tightly can act as a knife across the incision and cut the fascia as the wound swells or as tension is placed on the suture line.

The anatomic location and type of abdominal incision will influence how many layers of fascia will be sutured. The posterior fascial layer is always closed. The anterior layer may be cut and require suturing. Mass closure technics are increasing in popularity.

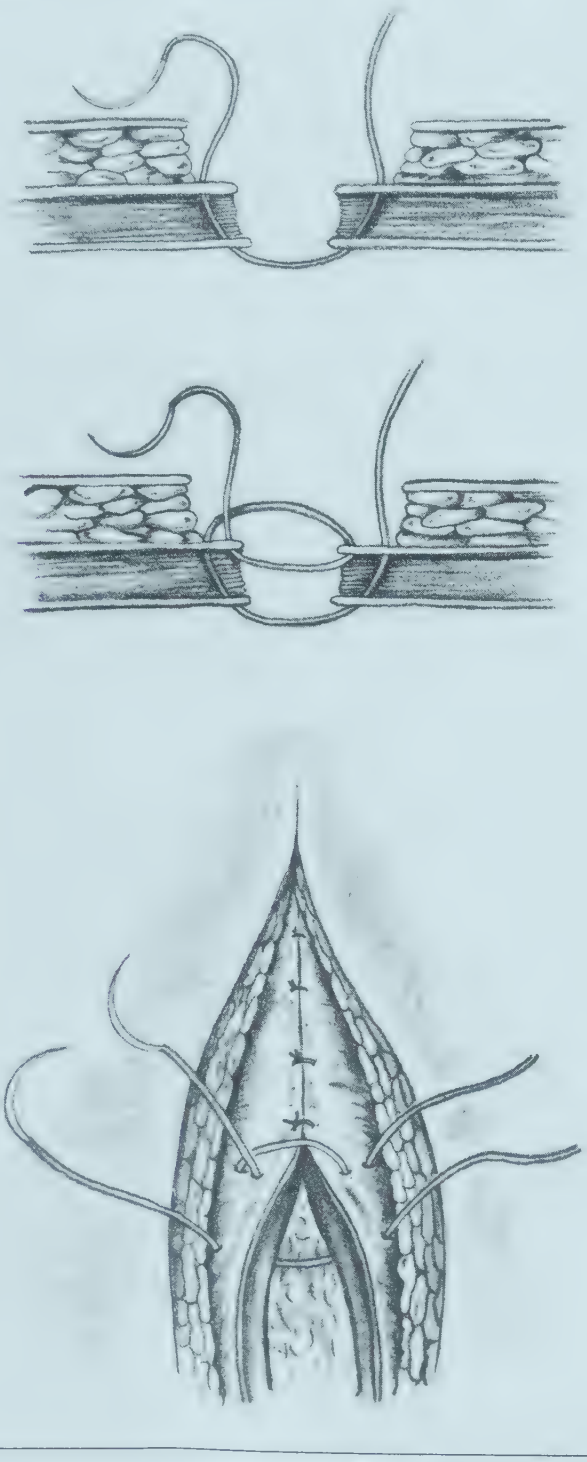
MUSCLE. Abdominal muscles may be either cut, split *(separated)* or retracted depending upon the location and type of the incision chosen. Where possible, the surgeon prefers to avoid interfering with muscular blood supply and nerve function by making a muscle-splitting incision or retracting the entire muscle towards its nerve supply. During closure, muscles handled in this manner need not be sutured. The fascia is sutured rather than the muscle so that normal motion in the muscle within the fascial sheath is not impaired.

Sutures, when placed in abdominal muscle tissue, are usually of the same material as that used for fascial closure.

3. Lehman JA et al: Prevention of abdominal wound disruption, *Surg Gynecol Obstet 126:* 1240-1241, June 1968
4. VanWinkle W, Salthouse TN: op cit, p. 10

SMEAD-JONES TECHNIC. Many surgeons use the Smead-Jones far-and-near technic for abdominal wound closure. This is a single layer closure through both layers of the abdominal wall fascia, abdominal muscles, peritoneum and anterior fascial layer *(Fig. 13)*. These interrupted sutures resemble the figure eight when placed. Either monofilament stainless steel or PROLENE suture is used. This closure is strong and rapid, provides good wound support during early wound healing with a low incidence of wound disruption, and has a low incidence of late incisional problems.

**Fig. 13 Smead-Jones abdominal wound closure technic**

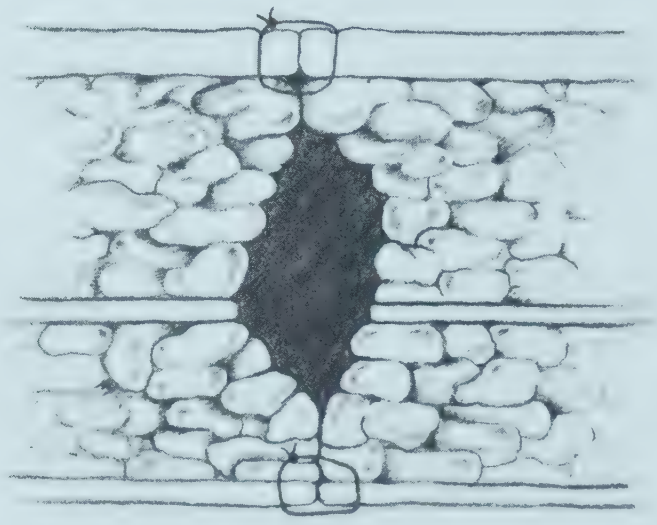


"Monofilament polypropylene sutures have the same general advantages of monofilament wire; they are strong, nonabsorbable, retain their strength after implantation, are inert, causing minimal tissue reaction, resist bacterial contamination or infection because of their monofilament design, and are well tolerated by patients in the late postoperative months. This latter feature is a major advantage over wire sutures."[5] One disadvantage of both stainless steel and PROLENE suture, especially in thin patients, is the lump caused by the knots underneath the skin. To correct this problem, knots can be buried underneath the fascia instead of in the subcutaneous space. "When using wire sutures, caution must be taken not to leave long free ends, since they could conceivably cause damage to the intraperitoneal viscera."[6]

SUBCUTANEOUS FAT. Neither muscle nor fat tolerates sutures particularly well. "The placement of subcutaneous sutures to obliterate dead space and to prevent hematoma must be examined critically.... The presence of a single suture of any type will drastically reduce the size of inoculum required to produce infection. Because fat is mostly water, there is little tensile strength; placing sutures in this layer for any reason is of questionable benefit."[7]

Some surgeons believe, however, that it is necessary to place a few sutures in a thick layer of subcutaneous fat to hold the wound edges together,

**Fig. 14 Dead space in subcutaneous fat**

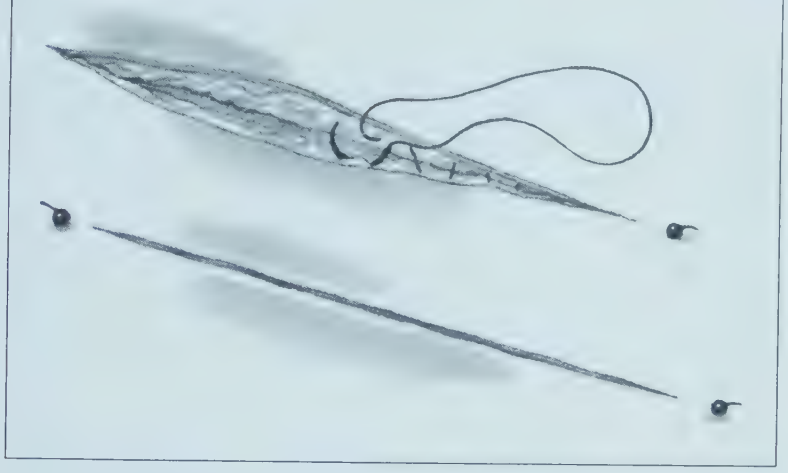


5. Hermann RE: Abdominal wound closure using a new polypropylene monofilament suture, *Surg Gynecol Obstet 138:* 86, Jan 1974
6. David TE, Hermann RE: Burying suture knots in abdominal wound closure, *Surg Gynecol Obstet 142:* 408, March 1976
7. Macht SD, Krizek TJ: Sutures and suturing–current concepts, *J Oral Surg 36:* 711, Sept 1978

especially in obese patients. Without good approximation, *dead spaces* will be left *(Fig. 14)*. Tissue fluids can accumulate in these pocket-like spaces, delaying healing and predisposing to infection. Absorbable material is usually selected for sutures in the subcutaneous layer. The surgeon may use the same material and size used earlier to ligate blood vessels in this layer.

SUBCUTICULAR. The subcuticular layer of tough connective tissue, if sutured, will hold the skin edges in close approximation when good cosmetic results are desired. With a single subcuticular layer closure, less evidence of scar gaping or expansion may be seen after a period of six to nine months than is seen with simple skin closure. Continuous short lateral stitches are taken beneath the epithelial layer of the skin. Either absorbable or nonabsorbable suture may be used. If a nonabsorbable is used, the suture strand comes out through

**Fig. 15 Continuous subcuticular closure anchored with lead shot**



the skin at each end of the incision. Usually a perforated lead shot is crushed tightly on each end to secure the suture until it is removed *(Fig. 15)*.

Where skin tension is not great, very fine sizes of subcuticular sutures can be used, for example in the face and neck. Larger sizes should be used for abdominal wounds where more stress may be put on the wound. If a hairline scar is the desired result, as on exposed areas such as the face, very close approximation of the skin is required. Skin closure tapes may be used to supplement subcuticular sutures. These should be left on the wound for an extended period. *(Refer to Section VIII, page 79)*.

When minimal scarring is a prime goal, some surgeons close both the subcuticular and skin layers. The material placed within the dermis "should be capable of maintaining its tensile strength at least through the collagen synthesis stage of healing–approximately six weeks. Clearly, the material should be nonabsorbable where tension is a significant factor. In other instances, chromic *(surgical)* gut or polymeric materials are acceptable. To reduce extrusion, care should be taken to avoid placing the sutures too close to the epidermal surface. Burying the knot also helps to keep the bulk of foreign material away from the free edge. After this layer is completed, the skin edges should be approximated."[8]

If the skin is nonpigmented and thin, a clear or white monofilament suture is usually invisible. Dyed sutures in the subcuticular layer sometimes may be seen through the skin.

SKIN. Skin is composed of epithelium and the underlying dermis. When a wound is made in skin, the epithelial cells in the basal layer at the margins of the wound flatten and commence to migrate into the wound area. These migrating cells move only on living tissue. Therefore, they move *down* the wound edge until living, undamaged tissue is reached at the base of the wound. They then migrate across the wound bed to establish contact with similar cells migrating from the opposite side of the wound.

Placement of a suture through the skin creates a wound. Epithelial cells migrate down the suture track. When the suture is removed, an epithelium-lined track through the dermis remains. Eventually, these cells disappear, but some may remain and form keratin. In any event, a punctate scar is usually seen on the skin surface and a typical "railroad track" appearance of the wound may result. This is relatively rare if the skin sutures are not placed with excessive tension and are removed by the seventh postoperative day.

Skin wounds regain tensile strength slowly. "However, it is common practice to remove skin sutures anywhere from three to ten days postoperatively, a time when the wound has only five to ten percent of the strength of unwounded tissue. The reason this is possible is that most wound stress is taken up by the fascia, and thus, skin is subjected to little tension."[9] Therefore, in closing most wounds, particularly in the abdomen, reliance is placed on fascial closure to hold the wound closed.

Skin or subcuticular sutures need only be strong enough to overcome the natural skin tension and keep the wound edges in apposition. "The width of the resultant scar will be the distance between the skin edges before the final layer is placed. The

8. Macht SD, Krizek TJ: op cit, p. 711
9. VanWinkle W, Hastings JC: Considerations in the choice of suture material for various tissues, *Surg Gynecol Obstet 135:* 115, July 1972

forces creating this distance between the edges of the wound will be present long after the sutures are removed, while significant collagen synthesis occurs *(from five to 42 days)*. After this time, gain in tensile strength of the wound is due mostly to remodeling, that is, cross-linking of collagen rather than de novo synthesis. Increased tensile strength will continue for up to two years but will never quite reach that of normal tissue."[10]

Suture technic for skin closure may be continuous or interrupted with either nonabsorbable or absorbable material. Skin edges should be everted. Since skin cannot be sterilized, only mechanically cleansed with an antiseptic agent, theoretically the suture strand should be passed through skin only once to eliminate the chance of cross-contamination along the entire suture line. For this as well as other reasons, interrupted technic is usually preferred. The skin is tough so that a sharp needle is of the essence for every stitch to minimize tissue trauma.

It must be remembered that skin sutures are exposed to the external environment. Contamination with exogenous microorganisms in the wound and suture tracks is a potential hazard leading to wound infection or stitch abscess. Multifilament sutures may provide a haven for microorganisms that can penetrate the interstices of the suture. The granulocyte and macrophages are too large to work their way between tightly braided or twisted suture filaments. Thus it can be appreciated that monofilament sutures are usually preferred for skin closure.

Monofilament sutures induce significantly less tissue reaction than multifilament sutures. All suture materials induce some tissue reaction that reaches a peak between two and seven days after implantation. After the seventh day the reactions to nonabsorbable and absorbable materials differ. The reaction around nonabsorbable sutures subsides and remains relatively acellular with maturing fibrous tissue forming a dense capsule around the suture. Reaction to absorbable suture remains relatively intense until the suture material absorbs or is removed, but is less with synthetic materials than with surgical gut.

"Skin closure usually does not require large sutures since the tension should be borne by the fascial or subcutaneous sutures. For cosmetic reasons, monofilament sutures, such as nylon or polypropylene, are preferred. However, many skin incisions are successfully closed with silk and polyester multifilaments. The key to success is early removal before epithelialization of the suture track occurs and before contamination is converted into infection."[11]

### *Closure with Retention Sutures*

Retention or stay sutures provide a secondary suture line. These sutures, placed at a distance from the primary suture line, relieve undue stress on the healing wound and help to obliterate dead space. Increased intraabdominal pressure resulting from vomiting, coughing, straining and distention can cause stress on the suture line in the postoperative period. When the surgeon anticipates that unusual stress may be placed on the primary suture line, or the patient is debilitated or obese, retention sutures are used as a protective measure against possible wound disruption.

Heavy sizes *(0 to #5)* of nonabsorbable materials are used as retention sutures. Suture materials available in the ETHICON* retention suture line are ETHILON* nylon suture, MERSILENE* polyester fiber suture, ETHIBOND* polyester suture, PROLENE suture, monofilament surgical steel and PERMA-HAND* silk suture. A large size suture is recommended not so much for its strength, as for the fact that the larger diameter is less likely to cut through tissue when a sudden rise in intraabdominal pressure occurs.

Properly placed retention sutures provide a strong method of holding an abdominal wound together. But they cause the patient more postoperative pain than a layered closure. If indicated, the best technic is to use a material with needles swaged on each end *(double-armed)* and place the sutures from the bottom of the wound toward the outside. This avoids pulling potentially contaminated epithelial cells through the entire abdominal wall. Retention sutures may be buried beneath the skin or brought out percutaneous. *(Refer to Section II, page 12, for technics for placement of retention sutures.)*

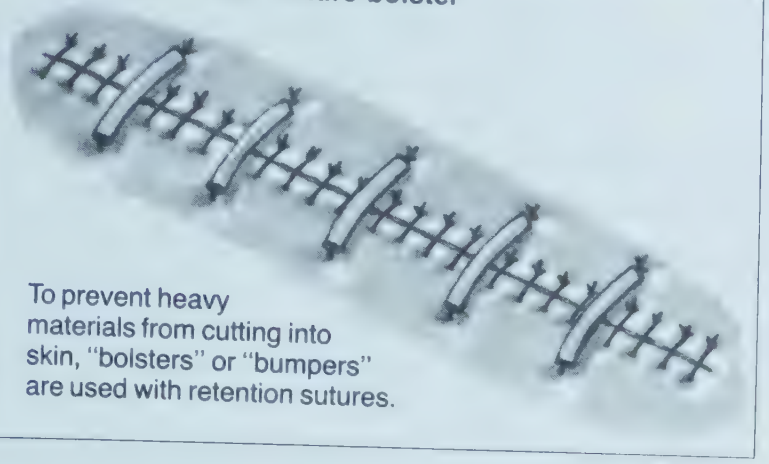
To prevent heavy materials from cutting into the skin under stress, one end of each retention suture may be threaded through a short length of plastic or rubber tubing before it is tied. These pieces of tubing are referred to as *bolsters* or *bumpers (Fig. 16)*. Plastic bridges also are used to protect the skin and primary suture line. *(See Section VIII, page 79).*

Because retention sutures are nonabsorbable, they should be removed as soon as danger of sudden increases in intraabdominal pressure is over. Usually they can be removed on the fourth or fifth postoperative day. In some situations delay may be

10. Macht SD, Krizek TJ: op cit, p. 711
11. VanWinkle W, Hastings JC: op cit, p. 125

*Trademark

Fig. 16 Retention suture bolster



To prevent heavy materials from cutting into skin, "bolsters" or "bumpers" are used with retention sutures.

the better part of valor. It is not uncommon to leave them 14 to 21 days in debilitated patients. Surgical steel or PROLENE sutures that cause minimal tissue reaction can be left in place for a prolonged period of two to three weeks without concern. The surgeon's judgment of the patient's condition is the controlling factor in suture removal.

Increasing popularization of mass closure technic is leading to less frequent use of retention sutures.

### Sutures for Drains

If a drainage tube is left in a hollow organ, such as the gallbladder, it may be secured to the wall of that organ with an absorbable suture.

A drainage tube inserted into the peritoneal cavity through a stab wound in the abdominal wall usually is anchored to the skin. This prevents the drain from slipping into or out of the wound. One or two stitches of a nonabsorbable material may be needed for this purpose.

## SUTURE NEEDS IN OTHER BODY TISSUES

### Sutures in Upper Alimentary Tract

The upper alimentary tract down to the cardiac sphincter of the esophagus must be considered a potentially contaminated area. The alimentary tract is a musculomembranous canal lined with mucus membranes. There appears to be no major clinical significance in the final healing of mucosal wounds on the basis of suture material alone, but rather on the technic with which they are placed.[12]

ORAL CAVITY AND PHARYNX. Oral and pharyngeal structures usually heal quickly if not infected. Absorbable sutures may be preferred and are usually more comfortable for patients, especially children. However, in certain circumstances, monofilament nonabsorbable sutures may find applications. The monofilament materials cause less severe tissue reaction than the multifilament materials in buccal mucosa. Nonabsorbable materials have the disadvantage of requiring removal. Wound tensions are usually not great in this area, and fine size sutures are adequate.

ESOPHAGUS. The esophagus is a difficult organ to suture. It does not have a serosal layer. The mucosa heals slowly. The thick muscular layer does not retain sutures well. Absorbable suture usually is preferred, but nonabsorbables also have been used successfully. If any of the multifilaments are used, penetration through the mucosa into the lumen should be avoided to prevent infection. "A particularly high incidence of anastomosis failure has been reported in operations on the esophagus."[13]

### Sutures for Respiratory Tract

Relatively few studies have been done on healing in the respiratory tract. Bronchial stump closure, following lobectomy or pneumonectomy, presents a particular problem. "If bronchopleural fistula is to be avoided following pulmonary resection, all methods of bronchial stump closure must be based upon fundamental principles of healing.... Infection, long stumps, and inaccurate approximation of the transected bronchus predispose to bronchopleural fistula. Other factors critical in bronchial stump healing are avoidance of tissue trauma and maintenance of blood supply to the area of closure."[14] Healing of the bronchial stump is slow or, in some instances, nonexistent. Unless it is closed tightly, air leaks into the thoracic cavity. Strong, closely spaced sutures afford an air-tight closure. Surgical steel, polyester or polypropylene appear to be the sutures of choice. Collagen production in the bronchial stump correlates with the severity of the inflammatory response of the closure material. These materials are the least reactive. "Because of the chance of infection, a monofilament suture is best."[15] Silk, cotton and nylon are more reactive, but lose strength with time and may permit secondary leakage. Absorbable sutures should be avoided for the same reasons.

### Sutures for Cardiovascular System

Although definitive studies are few, blood vessels

12. Macht SD, Krizek TJ: op cit, p. 712
13. Tera H, Aberg C: Tissue holding power to a single suture in different parts of the alimentary tract, *Acta Chir Scand 142:* 343, 1976
14. Scott RN et al: Bronchial stump closure techniques following pneumonectomy, *Ann Surg 184* (2): 205, 1976
15. VanWinkle W, Hastings JC: op cit, p. 124

appear to heal rapidly. However, most cardiovascular surgeons prefer to use synthetic nonabsorbable sutures for cardiac and peripheral vascular surgery. Lasting strength and leak-proof anastomoses are necessary.

VESSELS. Excessive tissue reaction can lead to decreased luminal diameter or to thrombus formation. Therefore, the more inert synthetics, nylon, polyesters or polypropylene, are the materials of choice for vessel anastomosis. The multifilament polyester sutures allow clotting to occur within the interstices and thus help prevent leakage at the suture line. The major advantage of a coated polyester suture, such as ETHIBOND suture, is its slippery surface that causes less friction when drawn through a vessel. Many surgeons find that PROLENE polypropylene suture is ideal for coronary artery procedures because it also does not "saw" through vessels.

Continuous sutures are used in large vessel anastomosis because the tension adjusts in such a way as to be distributed evenly around the circumference of the anastomosis. Continuous sutures also provide a more leak-proof closure than interrupted sutures. Interrupted monofilament materials, either ETHILON nylon sutures or PROLENE sutures, are used for microvascular anastomoses, however.

Special care must be taken in anastomosing major vessels in young children where further growth can be expected. Here silk can be used to advantage since it loses much of its tensile strength after about one year and usually disappears after two or more years. Continuous polypropylene has been reported to have been used in children without adverse effects. Apparently the continuous suture when placed, is a coil which, with growth, becomes stretched to accommodate to changing dimensions of the blood vessel. On the other hand, reports of stricture following vessel growth have stimulated interest in use of a suture line which is one half continuous and one half interrupted. Animal studies suggest that a prolonged absorbable suture may be the ideal suture giving adequate short-term support and permitting future vessel growth.

Mycotic aneurysms and infection are extremely serious complications following vascular trauma. "The term 'mycotic aneurysm' has come to include all those infected aneurysms, both true and false, that result from a variety of causes, including embolization, trauma or localized sepsis."[16] A suture can act as a nidus for infection or a hematoma. "A pseudoaneurysm can result from injury to the arterial wall with concomitant or subsequent infection of the hematoma. Localized sepsis can also spread to involve adjacent vascular structures with necrosis of the arterial wall."[17] In the presence of infection, extensive tissue damage arising from the chemical properties of a suture material might possibly lower the tissue's power to combat the progress of infection. The influence of this factor can be reduced by using suture materials known to cause no more than a mild tissue reaction.[18] While the chemical reactions of the vessels to the suture material are important, the physical properties of the material are significant. "Monofilament sutures are more desirable in vascular surgery than multifilament because of their lower infectability."[19]

PROSTHESES. The fixation of vascular prostheses and artificial heart valves present an entirely different suturing problem than vessel anastomosis. Here the sutures must retain their original physical properties and strength throughout the life of the patient. A prosthesis never becomes completely incorporated into the tissue and constant movement of the suture line occurs. Before it was recognized in the 1960s that silk is not a true nonabsorbable material, several disastrous results involving suture line rupture of vascular prostheses and dislodgement of artificial heart valves occurred due to degradation of silk sutures. Coated polyester fibers are the sutures of choice for fixation of vascular prostheses and heart valves. An interrupted technic is used for placement of heart valves. Many surgeons alternate green and white strands of ETHIBOND suture to place all the sutures around the cuff of the valve before tying the knots. ETHIBOND suture retains its integrity and strength indefinitely.

TEFLON® felt pledgets may be used as a buttress under sutures when the tearing of friable tissue is a possibility. Pledgets are most commonly used in valve replacement procedures to prevent the annulus from tearing when the prosthetic valve is seated and the sutures are tied. Some surgeons use pledgets routinely in valve surgery. Others use them in situations in which extreme deformity, dis-

16. Anderson CB et al: Mycotic aneurysms, *Arch Surg 109:* 712, Nov 1974
17. Ibid
18. Osterberg B, Blomstedt B: Effect of suture materials on bacterial survival in infected wounds, *Acta Chir Scand 145:* 433, 1979
19. Dineen P: The effect of suture material in the development of vascular infection, *Vasc Surg 11* (1): 32, 1977

tortion or tissue destruction at the annulus is encountered.

Either an interrupted technic or continuous suture may be used for vessel to graft anastomoses. When the graft can be held vertically, as in end-to-side aortic anastomoses, the interrupted technic usually is preferred. However, in technically difficult areas, such as the groin or popliteal fossa, a continuous suture of polypropylene may be helpful to accurately place the suture and reduce risk of anastomotic narrowing or hemorrhage.[20]

### Sutures for Urinary Tract

Closure of tissues in the urinary tract must be leakproof to prevent extravasation of urine into surrounding tissues. The same considerations that dictate the choice of suture material for the biliary tract also influence the decision for the urinary tract. Nonabsorbable sutures cannot be used because their presence incites the formation of urinary calculi. Absorbable sutures are uniformly used. Coated VICRYL *(polyglactin 910)* suture is "ideally suited for closing genitourinary wounds, since these organs regain wound strength rapidly and are essentially healed by 21 days. There is no need for a suture thereafter, and the disappearance of polyglactin 910 after 28 days is just what is desired for sutures in these locations."[21] The hydrolytic degradation of Coated VICRYL suture does not seem to be significantly affected by the acidic pH environment of the urinary tract.[22]

The urinary tract heals rapidly. The transitional cell epithelium migrates over denuded surfaces rapidly. Unlike other epithelium, the migrating cells undergo mitosis and cell division. Epithelial migration may be found along suture tracts in the body of the bladder.

Bladder wounds regain 100 percent of strength of the unwounded bladder wall within 14 days. After this time, there is no further gain in strength. The rate of collagen synthesis peaks at five days and declines rapidly thereafter. Thus, sutures should be needed for only about seven to ten days.

### Sutures for Female Genital Tract

The female genital tract is usually regarded as a potentially contaminated area. For this reason most gynecologists prefer to use absorbable sutures for repair of incisions and defects. Although some gynecologists prefer using heavy large size #1 surgical gut sutures, the stresses on these organs and the rate of healing would indicate that larger suture sizes actually may not be required, except for abdominal closure if that approach has been used for access to the pelvis. Because the gynecologist is frequently working in a very restricted field, handling qualities of the suture become important. The synthetic absorbable sutures also have application in this area. Gynecologists often prefer a size 0 of these suture materials for the tough muscular, highly vascular tissues in the pelvis and vagina. These tissues demand strength during approximation and healing.

### Sutures for Tendons

Tendons heal slowly. The fibroblasts within the body of the tendon do not participate in the healing reaction. The repair fibroblasts are derived from the peritendonous tissue and migrate into the wound. The junction heals first with scar tissue, and then by replacement with new tendon fibers. Maintenance of close apposition of the cut ends of tendons, particularly extensor tendons, is necessary for good functional results.

A suitable material and a satisfactory technic are two critical factors in tendon repair. The material should be inert and strong. Tendon ends tend to separate due to muscle pull. Thus, sutures with great degrees of elasticity are not desired. Surgical steel is widely used in tendon repair because of its durability and its lack of elasticity. Any of the synthetic nonabsorbable materials, polyester fibers, polypropylene or nylon, may be used. Most tendon injuries are due to traumatic circumstances and a dirty wound may be involved. In the presence of potential infection, the most inert suture materials are preferable.

The suture should be placed in such a way to cause the least possible interference with the surface of the tendon, which is part of the gliding mechanism. Also, there should be a minimum interference with the blood supply of the tendon. The method of insertion should prevent separation of the ends. The parallel arrangement of the tendon fibers in a longitudinal direction makes permanent and secure placement of sutures difficult. Various figure-of-eight and other types of suturing have been resorted to in order to prevent suture slippage and the formation of gaps between the cut ends of the tendon. Many surgeons use the Bunnell technic.

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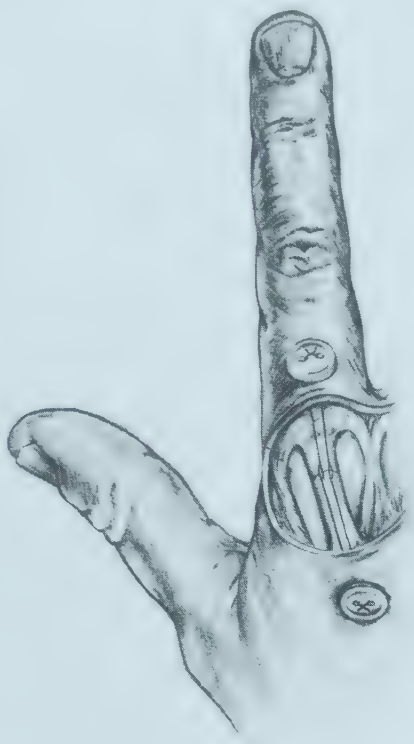
20. McCollum CN, Kester RC: A sliding suture technique for inaccessible arterial anastomoses, *Surg Gynecol Obstet 153* (6): 907, 1981
21. VanWinkle W: The healing of skin and visceral wounds and the effect of suture materials, *Symposium on Basic Science in Plastic Surgery*, St. Louis: Mosby, 1976, p. 135
22. Chu CC: A comparison of the effect of pH on the biodegradation of two synthetic absorbable sutures, *Ann Surg 195* (1): 55, 1982

The suture is placed for withdrawal when its function as a holding structure is no longer necessary. Referred to as a *pull-out suture*, the suture is brought through the skin and fastened over a button *(see Fig. 17)*.

**Fig. 17 Tendon pull-out suture with polypropylene button**



### Sutures for Bone

Usually bone is not sutured. However, for making attachments of tendons to bone, wire sutures are frequently used with good results. Such healing is slow and a permanent material is required. Periosteum heals fairly rapidly and, if suturing is necessary, surgical gut or Coated VICRYL suture may be used. In fact, almost any suture is satisfactory in this location.

If bony structures are to be sutured, such as may be the case in facial fractures, monofilament surgical steel sutures are generally preferred since their lack of elasticity is an asset where immobilization of the fracture line is needed. Facial bones do not heal by callus formation and fibrous union is common. The suture material must be in place for a long period of time until the fibrous tissue is laid down and remodeled. This may take several months, and during this period the sutures must keep the structure immobile and in good apposition. Steel sutures are ideally suited for this purpose.

Interrupted surgical steel sutures usually are used for closure of the sternum after median sternotomy. "Occasional difficulties are encountered related to manual technic for suture wire application and approximation. Asymmetric twisting of the wire leads to potential wire buckling, metal fatigue, and subsequent wire fracture. Incomplete wire fixation under these circumstances will result in motion between the approximated sides of the sternum, resulting in postoperative pain and possible dehiscence."[23] An equally serious complication is painful nonunion. Effective median sternotomy closure requires approximation of the sternum under appropriate tension.

### Sutures for Nervous System

Neurosurgeons have traditionally used an interrupted technic to close galea and dura. Surgical silk sutures continue to be the material of choice for its pliability and ease of knot tying. The only disadvantage to using silk is that much foreign body reaction is evidenced. To avoid this, many surgeons have switched to NUROLON braided nylon suture for ease in tying, greater strength and less tissue reaction. In addition, PROLENE suture has found acceptance with surgeons who prefer a continuous suture closure technic and for use in potentially infected areas.

According to Vallfors et al, "VICRYL *(suture)* seems to be the best material for dural suturing as it produces less tissue reaction and side effects than do other materials....The lack of adhesions with this material is an advantage if reoperation is necessary. VICRYL *(suture)* keeps its tensile strength as long as it is needed, and absorption is almost completed when the incision has healed."[24]

In peripheral nerve repair, suture gauge and needle delicacy must be consistent with nerve size. Suturing of a peripheral nerve precisely often requires the aid of an operating microscope. Only the epineurium, the outer sheath, is sutured after the motor and sensory fibers are properly realigned. "Suture strength is not an important consideration. The basic need is for a suture which incites the least inflammatory and fibroplastic reaction. Thus, surgical gut, silk, and cotton should not be used. On the other hand, fine sizes of nylon, polyester and polypropylene sutures can be advantageous."[25]

### Sutures for Eye

The eye presents special problems in healing. The

23. Cohn JD, Valente dos Santos, M: Sternal wire closure by an instrumental method, *Am J Surg 132:* 668, 1976
24. Vallfors B et al: Absorbable or nonabsorbable suture materials for closure of the dura mater?, *Neurosurgery 9* (4): 410, Oct 1981
25. VanWinkle W, Hastings JC: op cit, p. 124

ocular muscles and the conjunctiva and sclera have good blood supplies; the cornea, on the other hand, is an avascular tissue. Although epithelialization of the cornea is rapid in the absence of infection, full thickness corneal wounds heal slowly. Thus, in closing corneal wounds such as cataract incisions, sutures should remain in place for about three weeks. Operations for muscle recession, which involve suturing muscle to sclera, do not require sutures for more than about one week.

Formerly, silk was the preferred suture material for ophthalmologic surgery. However, in the cornea, silk sutures can be irritating and may have to be removed. Fine size absorbable suture is currently used for many ocular procedures. Occasionally, the sutures are absorbed too slowly in muscle recessions and produce granulomas in the sclera. Too rapid absorption has, at times, been a complaint in cataract surgery. Polyglactin 910 is useful in cataract and muscle surgery because of its dependable behavior and because it induces less cellular reaction than surgical gut.

Use of the operating microscope has increased dramatically. The ophthalmologist can choose from among many fine size suture materials for keratoplasty, cataract and vitreous-retinal microsurgical procedures. The monofilament materials include ETHILON suture, PROLENE suture, PDS* *(polydioxanone)* suture and VICRYL monofilament suture. Braided materials such as virgin silk, black braided silk, MERSILENE suture and Coated VICRYL suture also are available for ophthalmic use.

### Sutures for Microsurgery

The use of the operating microscope was enhanced by the introduction of fine sizes of sutures and needles. ETHILON nylon sutures, sizes 8-0 through 11-0 were the first microsurgery sutures available. Since then the microsurgery line has expanded to include PROLENE suture and Coated VICRYL suture. Literally all surgical specialties perform some procedures under the operating microscope, especially vascular and nerve anastomoses.

### Sutures for Contaminated Wounds

Contamination exists when microorganisms are present, but their numbers are not so great that the body defenses cannot dispose of them locally. Infection exists when the level of contamination reaches a point where local tissue defenses cannot cope with the invading microorganisms. The level at which contamination becomes infection, for most organisms, is about $10^6$ bacteria per gram of tissue in an immunologically normal host. Wounds that are inflamed without discharge and those that drain culture-positive serous fluid are considered possibly infected. They are definitely infected if purulent discharge is present. *(Refer to classification of operative wounds on pages 5 and 6.)*

Contaminated wounds can be converted to infected wounds when hematomas, necrotic tissue, devascularized tissue or large amounts of devitalized tissues, especially muscle, fascia and bone are present. Microorganisms can multiply in such circumstances, safe from the cells that provide the local tissue defenses. After irrigation and debridement, some contaminated wounds may be suitable for closure. Other wounds are left open to heal by second intention.

Foreign bodies, including sutures, foster the persistence of localized infection. "The proper technical use of sutures, therefore, becomes important with particular emphasis on the surgeon's attention to the types of sutures, their spacing, the depth of 'bites' taken, and the degree of tension necessary to bring tissues in apposition."[26]

Monofilament suture material is preferred in contaminated and infected wounds. Multifilament sutures may provide a haven for microorganisms. Organisms can penetrate the interstices of the suture, but granulocytes and macrophages are too large to work their way between tightly packed suture filaments. Normal absorption or encapsulation of these sutures is delayed in the presence of infection and inflammation of the tissues is prolonged.[27]

## PRINCIPLES OF SUTURE SELECTION

The surgeon has a choice of suture materials from which to select for use in body tissues. Adequate strength of the suture material will prevent suture breakage. Secure knots will prevent knot slippage. But the surgeon must understand the nature of the suture material, the biologic forces in the healing wound, and the interaction of the suture and the tissues. The following principles should guide the surgeon in suture selection.

1) When a wound has reached maximal strength, sutures are no longer needed.
   Therefore:
   a. Tissues that ordinarily heal slowly such as skin, fascia and tendons should usually be closed with nonabsorbable sutures.

26. Altemeier WA et al (ed): *Manual on Control of Infection in Surgical Patients*, Philadelphia: Lippincott, 1976, p. 127
27. Bucknall TE: Abdominal wound closure: Choice of suture, *J Royal Soc Med 74:* 580-585, 1981

*Trademark

b. Tissues that heal rapidly such as stomach, colon and bladder may be closed with absorbable sutures.

2) Foreign bodies in potentially contaminated tissues may convert contamination to infection.
Therefore:
   a. Avoid multifilament sutures which may convert a contaminated wound into an infected one.
   b. Use monofilament or absorbable sutures in potentially contaminated tissues.

3) Where cosmetic results are important, close and prolonged apposition of wounds and avoidance of irritants will produce the best result.
Therefore:
   a. Use the smallest inert monofilament suture materials such as nylon or polypropylene.
   b. Avoid skin sutures and close subcuticularly, whenever possible.
   c. Under certain circumstances, to secure close apposition of skin edges, skin closure tape may be used.

4) Foreign bodies in the presence of fluids containing high concentrations of crystalloids may act as nidus for precipitation and stone formation.
Therefore:
   a. In the urinary and biliary tract, use *rapidly absorbed sutures*.

5) Regarding suture size:
   a. Use the finest size, commensurate with the natural strength of the tissue.
   b. If the postoperative course of the patient may produce sudden strains on the suture line, reinforce it with retention sutures. Remove them as soon as the patient's condition is stabilized.

SECTION V

# Surgical Needles

## PHYSICAL CHARACTERISTICS OF SURGICAL NEEDLES

"Although, ideally, the needle to which the suture material is attached should play no role in wound healing, inappropriate selection of needles may prolong the conduct of the operation and may damage the tissues being sutured. Such needless damage to the structural integrity of the tissues may produce necrosis of the tissue with or without complicating infection and possibly failure to maintain approximation of tissues. Wound dehiscence with evisceration may occur, or incisional hernia and other wound complications, such as intestinal anastomotic leaks, bleeding, fistulization and the like, are possible, depending upon the tissues sutured and the area of the body in which the wound is made."[1]

Necessary for the placement of sutures in tissues, surgical needles must be designed to carry suture material through tissues with minimal trauma. They must be sharp enough to penetrate tissues with minimal resistance. They should be rigid enough to resist bending, yet flexible enough to bend before breaking. They must be sterile and corrosion-resistant to prevent introduction of microorganisms or foreign bodies into the wound.

To meet these requirements, the best surgical needles are made of high quality heat treated steel. Surgical needles made of carbon steel may corrode, leaving pits that can harbor microorganisms. Stainless steel is noncorrosive. The heat treating process is designed to give the needle maximum possible strength and ductility. Ductility is the ability of the needle to bend to a given angle under a given amount of pressure, called *load*, without breaking. This feature is sometimes referred to as malleability. The strength of a needle is determined in the laboratory by bending the needle 45 degrees. The force required to accomplish this bend is a measurement of the strength of the needle. If a needle is weak, it will bend too easily when passed through tissue. All ETHICON* stainless steel alloy needles are heat treated to have sufficient and consistent strength to perform satisfactorily in the body tissues for which they are designed. However, if too great a force is applied to a needle it may break, but it will bend before breaking. If a surgeon feels a needle bending, this is a signal that excessive force is being applied.

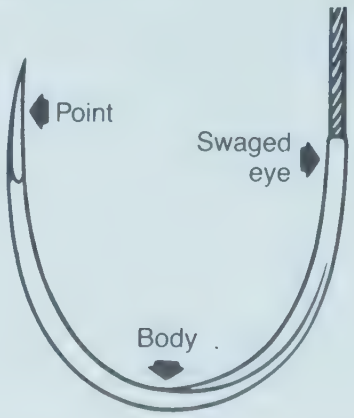
Precision made points, electropolishing and a SUPER-SMOOTH finish permit controlled penetration of needles and smooth passage through tissue. Most of the needles manufactured by ETHICON, INC., have a micro-thin silicone finish which significantly and measurably improves ease of needle penetration. According to laboratory tests, the force necessary to make initial penetration and the drag force on the needle body during the remainder of its passage through tissue are reduced by the use of this coating. A silicone coating is not put on ophthalmic needles because it would leave a residue in the transparent cornea.

Of many types available, the specific needle selected for use is determined by the type of tissue to be sutured, its location and accessibility, size of the suture material, and the surgeon's preference. "The mechanical characteristics of tissue, such as tensile strength, shear strength, weave, penetrability, density, elasticity and thickness, would seem to be mechanical factors that should be considered in the choice of a needle and suture. Since tensile and shear strength of the tissue would, in fact, appear to be more important than the ability of the suture material to maintain the tissues in apposition, one should then concentrate on the characteristics of weave, penetrability, density, elasticity and thickness of the tissue, all of which affect passage of the needle through it."[2]

## BASIC NEEDLE DESIGN

Regardless of ultimate intended use, all surgical needles have three basic components: the eye, the body and the point, as shown in *Fig. 18*.

**Fig. 18 Needle components**




1. Trier WC: Considerations in the choice of surgical needles, *Surg Gynecol Obstet 149:* 84, July 1979
2. Ibid, p. 86

*Trademark

## Eye

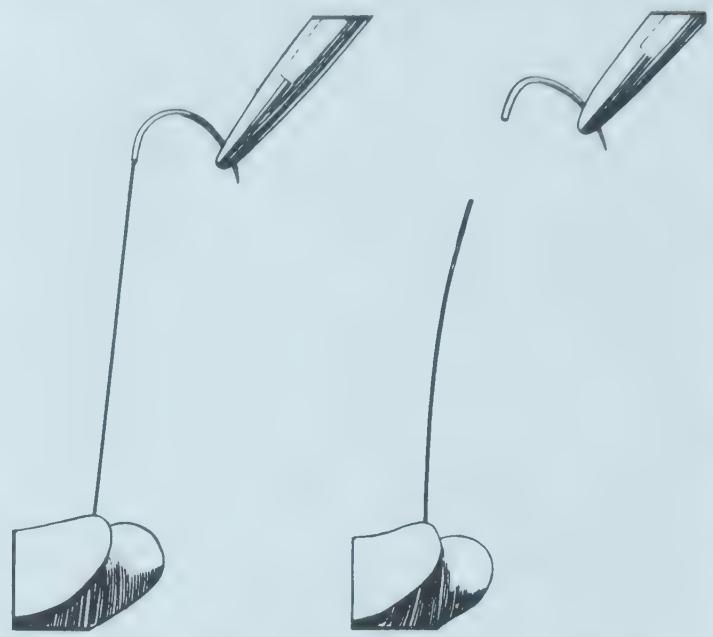
The eye falls into one of three categories: closed eye, French *(split or spring)* eye, or swaged *(eyeless)*. The closed eye is similar to a household sewing needle. The shape of the eye, which is enclosed, may be round, oblong or square. French eye needles have a slit from inside the eye to the end of the needle with ridges that catch and hold the suture in place. Eyed needles must be threaded. This presents the disadvantage of having to pull a double strand of suture material through tissue. The technic of threading eyed needles is shown in *Fig. 27*. This is a time consuming procedure for the scrub nurse. The needle may become unthreaded while the surgeon is using it. Tying the suture to the eye lessens this possibility, but further increases the bulk of suture material drawn through the tissue.

Approximately 80 percent of the sutures used today have appropriate needles attached by the manufacturer. These are called *swaged sutures*. A swaged *(eyeless)* needle has either a drilled hole in the end of it for insertion of the end of the suture, or a channel at the end of the needle. The drilled hole or channel is closed around the suture in the swaging process. In swaging, extreme care is taken to insure that the suture is securely encased in the drilled hole or channel. Each drilled hole and channel is specifically designed to accommodate the suture swaged into it. Needle and suture strand are joined together into a continuous unit that is convenient to use and minimizes trauma.

ATRALOC* surgical needles are eyeless needles permanently swaged to the suture strand. The attachment of the needle to the suture material must be secure so that the needle will not separate from the suture under normal use.

CONTROL RELEASE* needles are an adaptation of swaged needles which facilitate fast separation of the needles from the suture material when desired by the surgeon. The needle is securely attached to the suture strand, but it can be removed from the suture with a slight straight tug on the needleholder by the surgeon as illustrated in *Fig. 19*. These needles are used for interrupted suturing technics. They allow the placement of many sutures rapidly.

**Fig. 19 CONTROL RELEASE* needle suture**



1. The needle is held securely in holder. Suture is grasped securely just below needle, pulling strand taut.

2. The needle is released with a straight tug of the needleholder.

## Body

The body or shaft is the portion usually referred to as the needle grasping area. The cross sectional configuration of the body may be round, oval, side-flattened rectangular, triangular or trapezoidal. The oval, side-flattened rectangular and triangular shapes may be fabricated with longitudinal ribs on the concave or convex surfaces. This feature reduces rotational movement of the needle in the needleholder during suturing.

The longitudinal shape of the body may be straight, half-curved, curved or compound curved. *Fig. 20* relates anatomic sites and tissues to typical applications for each body shape.

### *Straight*

When the tissue is easily accessible, a straight needle may be preferred. Most of these needles are designed to be finger-held on or near the surface. Thus, they are used when direct digital manipulation can be performed easily. The Keith needle is a straight cutting needle used primarily for skin closure of abdominal wounds. Keith needles of varying lengths are used for suturing the meniscus in the knee through the arthroscope. They are also used manually or with a device *(see PROXIMATE* PSD purse string device, page 60)* to create a purse-string for intraluminal stapling of a gastrointestinal anastomosis.

Bunnell needles with cutting edges are used for tendon repair. Taper point milliner needles may be used for suturing the gastrointestinal tract. Some microsurgeons prefer straight needles for nerve

*Trademark

and vessel repair. The straight transchamber needle is designed to protect endothelial cells and to facilitate placement of intraocular lens.

*Half-curved*

The half-curved, or ski, needles may be used to close skin. However, because they are difficult to handle, these needles are rarely used. The curved portion passes through tissue easily while the remaining straight portion of the body is unable to follow the curved path of the needle without bending or enlarging the path in the tissue.

*Curved*

In most procedures, quick needle turnout from tissue is an advantage. Therefore, curved needles are the most frequently used shape. They require a smaller space for maneuvering the needle than straight needles.The curvature may be ¼, ⅜, ½ or ⅝ circle. The length of the arc in degrees determines the curvature. Needleholders must be used to manipulate curved needles.

Selection of the length, width and curvature of the needle depends on the size and depth of the area and the type of tissue to be sutured. Use of the ¼ circle needle is limited to ophthalmic and microsurgical procedures.

Probably the most commonly used curved needle is the ⅜ circle. These needles can be easily manipulated in relatively large and superficial wounds with slight pronation of the wrist. However, because a larger arc of manipulation is required, ⅜ circle needles are awkward or impossible to use in deep cavities, such as the pelvis or other relatively small inaccessible locations.

A ½ circle needle is easier to use in confined locations, although it requires more pronation and supination of the wrist. The tip of even a ½ circle needle may be obscured by tissue deep in the pelvic cavity, for example. The surgeon may have difficulty locating the point to reposition the needleholder and pull the needle through. A ⅝ circle needle may be more useful in this situation. The ⅝ circle needles are used in many urogenital operations and some intraoral and cardiovascular procedures.

*Compound Curved*

The compound curved needle, originally developed for anterior segment ophthalmic surgery, allows precise, uniform bites of tissue. The tight curvature of 80 degrees from the tip follows into a 45 degree curvature throughout the remainder of the body. The initial curvature of the needle produces reproducible, short, deep bites into the tissue. The curvature of the remaining portion of the body forces the needle out of the tissue, everting the wound edges and permitting a view into the wound. Equidistance of the suture material is assured on both sides of the incision. Equalized pressure on both sides of the corneal-scleral junction minimizes the possibility of astigmatism following anterior segment surgery.

**Point**

The point is from the extreme tip of the needle to the maximum cross section of the body. Sharpness of needle point, shape and size of the body are important characteristics to the surgeon. Success of the operation may depend on meticulous approximation of the tissues.

Each specific point is designed and produced to the required degree of sharpness to smoothly penetrate the types of tissues to be sutured. The basic needle shapes are cutting, TAPERCUT* surgical needle, tapered and blunt. *Fig. 21* shows the point and body shapes and typical applications.

*Cutting*

Cutting needles have at least two opposing cutting edges. These edges are honed so they will cut through tissue that is tough and difficult to penetrate. Cutting needles are "ideal for skin sutures that must pass through the dense, irregular and relatively thick connective tissue of the dermis. Because a significant length of the needle has a cutting edge, care must be taken in tissue with a thin layer of dense, irregular connective tissue, such as tendon sheath or oral mucous membrane, to avoid cutting through more of the tissue than desired."[3]

CONVENTIONAL CUTTING. A conventional cutting needle has two opposing cutting edges with a third cutting edge on the apex of the triangular configuration. This edge is on the *inside* concave curvature of curved needles. The cross sectional shape changes from a triangular cutting blade to a flattened body on both straight and curved needles. Curved needles may be prone to cut out tissue since the inside cutting edge cuts toward the edges of the incision or wound.

The Precision Cosmetic needle, although it has a conventional cutting point, has a unique design for aesthetic plastic surgery. The point is narrower for superior penetration of soft tissue. Penetration is

3. Ibid, p. 89

*Trademark

**Fig. 20 Needle body shapes and typical applications in anatomic sites and tissues**

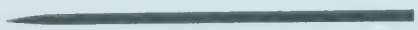
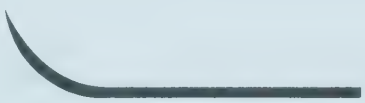
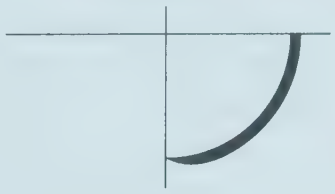
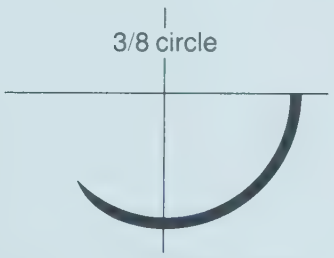
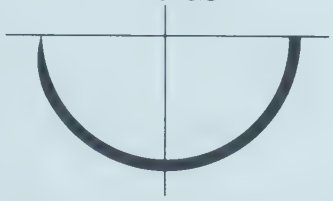
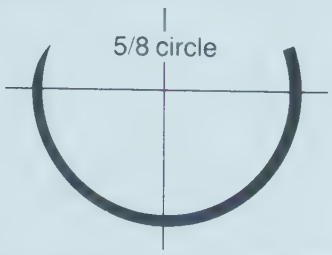
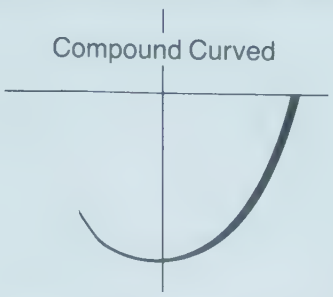
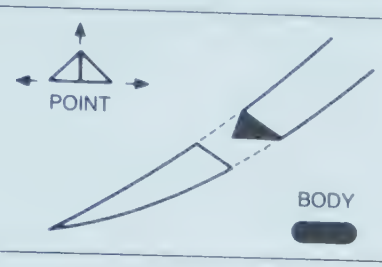
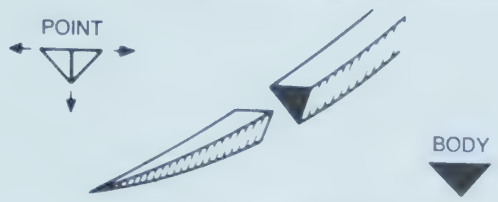
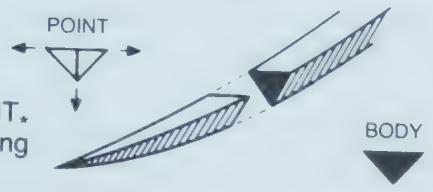
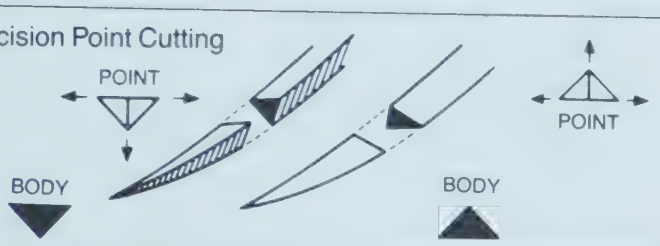
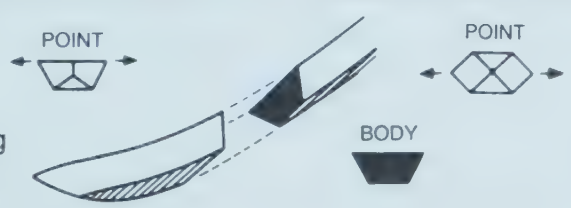
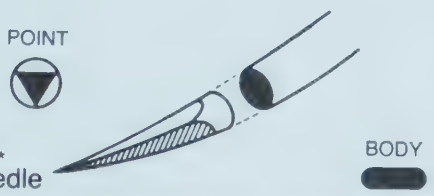
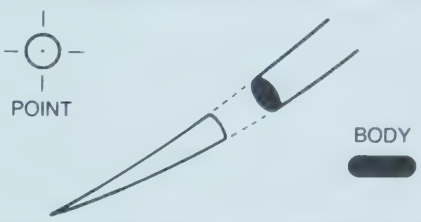
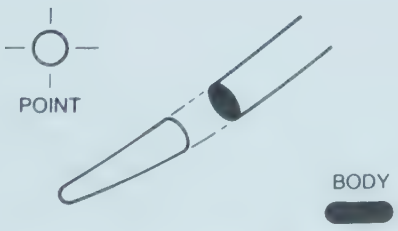
| Shape | Typical Applications | |
|---|---|---|
|  Straight | Gastrointestinal tract<br>Nasal cavity<br>Nerve<br>Oral cavity | Pharynx<br>Skin<br>Tendon<br>Vessels |
|  Half-curved | Skin, rarely used | |
| 1/4 circle  | Eye, primary application | Microsurgical procedures |
| 3/8 circle  | Aponeurosis<br>Biliary tract<br>Dura<br>Eye<br>Fascia<br>Gastrointestinal tract<br>Muscle<br>Myocardium | Nerve<br>Perichondrium<br>Periosteum<br>Peritoneum<br>Pleura<br>Tendon<br>Urogenital tract<br>Vessels |
| 1/2 circle  | Biliary tract<br>Eye<br>Gastrointestinal tract<br>Muscle<br>Nasal cavity<br>Oral cavity<br>Pelvis | Peritoneum<br>Pharynx<br>Pleura<br>Respiratory tract<br>Skin<br>Subcutaneous fat<br>Urogenital tract |
| 5/8 circle  | Cardiovascular system<br>Nasal cavity<br>Oral cavity<br>Pelvis<br>Urogenital tract, primary application | |
| Compound Curved  | Eye, anterior segment | |

**Fig. 21 Needle points and body shapes with typical applications**

| Needle Point and Body Shape | Typical Application |
|---|---|
|  Conventional Cutting | Ligament<br>Nasal cavity<br>Oral cavity<br>Pharynx<br>Skin<br>Tendon |
|  Reverse Cutting | Fascia<br>Ligament<br>Nasal cavity<br>Oral mucosa<br>Skin<br>Tendon sheath |
|  MICRO-POINT* Reverse Cutting Needle | Eye |
| Precision Point Cutting  | Plastic or cosmetic procedures<br>Skin |
|  Side-cutting Spatulated | Eye, primary application<br>Microsurgical procedures<br>Reconstructive ophthalmic procedures |
|  TAPERCUT* Surgical Needle | Bronchus<br>Calcified tissue<br>Fascia<br>Ligament<br>Nasal cavity<br>Oral cavity<br>Ovary<br>Perichondrium<br>Periosteum<br>Pharynx<br>Tendon<br>Trachea<br>Uterus<br>Vessels, sclerotic |
|  Taper | Aponeurosis<br>Biliary tract<br>Dura<br>Fascia<br>Gastrointestinal tract<br>Muscle<br>Myocardium<br>Nerve<br>Peritoneum<br>Pleura<br>Subcutaneous fat<br>Urogenital tract<br>Vessels |
|  Blunt | Blunt dissection through friable tissue<br>Kidney<br>Liver<br>Spleen<br>Uterine cervix for ligating incompetent cervix |

*Trademark

also improved by the fine wire diameter and finer taper ratio. The inside and outside curvatures of the body are flattened in the needle grasping area for greater stability in the needleholder. The needle is side-flattened to reduce bending that might occur due to the fine wire diameter. Where cosmetic results are important, the Precision Cosmetic needle is superior to any other for more delicate surgery, especially facial.

The configuration of the tip of the conventional cutting sternotomy needle is slightly altered to resist bending as it penetrates the sternum. The conventional cutting edges of the point extend from the round body approximately ¼ inch *(6 mm)* and terminate in a pyramidal shaped tip. The alloy used for this needle provides the increased strength and ductility needed for its function. This particular sternotomy needle maximizes cutting efficiency and control in the needleholder.

REVERSE CUTTING. The reverse cutting needle differs from the conventional cutting configuration in that the third cutting edge is located on the *outer* convex curvature of the needle. This design offers the advantage of having the flat surface closest to the edges of the incision or wound. This greatly reduces the danger of tissue cut out. The hole left by the needle leaves a wide wall of tissue for the suture to be tied against.

Greater force is usually directed toward the concave side of the needle because most surgeons find it easier to insert the needle with a forehand supinating stroke rather than a backhand pronating stroke. Reverse cutting needles are 20 percent stronger than similar sized conventional cutting needles. The flat base on the inner concave curvature also offers additional stability of the needle in the needleholder.

Some MICRO-POINT* surgical needles, especially designed for use in ophthalmic surgery, have reverse cutting edges. Each needle must be honed to extreme sharpness with a smooth surface. Each needle is manufactured under rigid specifications and inspected under high power magnification. This delicate "instrument" has made it possible for ophthalmic surgeons to suture the extremely tough tissues of the eye with optimum precision and ease.

Most of the Precision Point needles, designed for plastic or cosmetic surgery, have reverse cutting edges. Minimal trauma, early regeneration of tissue and little scar formation are of prime concern. The Precision Point reverse cutting needle assures smooth passage through tissue, placement in tissue for superior apposition, and a minute needle path. These needles are honed an additional 24 times more than other cuticular reverse cutting needles.

OS needles are curved heavy bodied reverse cutting edge needles designed for the extremely tough tissues, such as fascia, sutured by the orthopaedic surgeon. They are flattened and ribbed to provide increased stability in the needleholder where force is required to penetrate through tissue.

Many surgeons use curved reverse cutting needles to cut through dense, difficult to penetrate tissue, such as skin, tendon sheath or oral mucosa. Retention needles also have reverse cutting edges.

Cuticular and OS needles carry the third cutting edge all the way back to the swage. On the Precision Point needle, the bottom third cutting edge flattens out to one third to one half the length of the needle so that the top and bottom of the needle body is flat for security in the needleholder. This is an important feature for the plastic surgeon who uses smooth-jawed needleholders.

SIDE-CUTTING. Referred to as spatula needles, side-cutting needles are flat on top and bottom. This unique feature eliminates the undesirable tissue cut out of other cutting needles. Designed for ophthalmic surgery, the side-cutting edges enable the needle to separate or split through the thin layers of scleral or corneal tissue and travel within the plane between them. The optimum width, shape and precision sharpness of these needles insures maximum ease of penetration and control of the needle as it is passed between or through tissue layers. The position of the point varies with the design of each specific type of spatulated needle.

MICRO-POINT spatula needles and most SABRELOC* spatula needles have two cutting edges and trapezoidal shaped bodies. The SABRELOC needle with a cobra shaped tip has four equidistant defined cutting edges. The position of the point varies with the design of each specific type of spatulated needle.

By a unique honing process, the spatulated edges on TG "Plus" needles have a long, sharp, slim tip. They are made of a harder, stronger stainless steel alloy than other side-cutting needles. These needles are used for anterior segment surgery where multiple passes through tough tissue are necessary. They also are side-flattened for extra strength and stability in a microsurgical needleholder.

Ophthalmic Plastic Surgery (OPS) needle was designed for use in reconstructive ophthalmic

*Trademark

procedures, specifically the medial canthal ligament repair. This is a spatulated Precision Point needle.

All side-cutting spatulated needles are manufactured under the same exacting standards as the MICRO-POINT reverse cutting needles, undergoing 128 separate production steps with strict quality control checks at each step. MICRO-POINT spatula needles are used in microsurgery procedures when a cutting needle is desirable.

### *TAPERCUT* Surgical Needle*

The design of the TAPERCUT surgical needle is a blend of features of both the reverse cutting edge and taper point needles. Three cutting edges extend approximately 1/32 inch back from the point. These blend into a round taper body. All three edges of the point are sharpened to provide uniform cutting action. This point, sometimes referred to as a trocar point, readily penetrates dense tough tissue. The taper body portion provides smooth passage through tissue and eliminates the danger of a full cutting edge cutting further into the surrounding tissue.

Although initially designed for use in cardiovascular surgery on sclerotic or calcified tissue, TAPERCUT needles are widely used by many surgeons for suturing dense, fibrous connective tissue. They may be advantageous for fascia, periosteum and tendon when separation of parallel connective tissue fibers could occur with a cutting needle. They have application where a cutting point is needed and a smooth narrow-bodied needle is desirable.

A modified TAPERCUT needle was developed for anastomosis of small fibrotic and calcified blood vessels. It has a slimmer geometry than other TAPERCUT needles from the body through the point. The calcified portion of an artery requires a cutting tip only for initial penetration to avoid tearing the vessel. This geometry enhances ease of penetration. It also minimizes risk of leakage from friable vessels or vascular graft material.

TAPERCUT needles, ¼ circle, are used by microsurgeons when a minimal cutting tip is required for ease of penetration into a vessel, nerve, tube or the vas, without excessive trauma.

### *Taper*

Sometimes referred to as round needles, taper point needles are round only in the portion just behind the tip. The body tapers to a sharp point at the tip. The body is flattened into an oval shape. This cross sectional increased width helps prevent twisting or turning in the needleholder.

The taper point needle is usually preferred where the smallest possible hole in the tissue and minimum tissue damage are desired. This is particularly desirable in intestinal anastomosis, for example, to prevent leakage which can subsequently result in contamination of the abdominal cavity. The hole made by this needle point is no larger than the diameter of the needle. Taper point needles are used primarily on soft, easily penetrated tissues, such as the peritoneum, abdominal viscera, myocardium, dura and subcutaneous tissue. "They are also ideal for fascia since they minimize the accidental tearing of the thin connective tissue lying between patterned parallel and interlacing bands of denser connective tissue, such as the aponeurosis of the external oblique abdominal muscle or the fascia of the rectus abdominus muscle."[4]

MO needles have a taper point, but a heavier and more flattened body than conventional taper needles. These needles were designed for use in dense tissue, particularly for gynecology, general closure and hernia repair.

### *Blunt*

The blunt point needle can literally be used to dissect through friable tissue rather than piercing it. This needle has a taper body with a rounded blunt point that will not cut through tissue. It has application in blunt dissection and for suturing of friable parenchymal tissue, such as liver and kidney. It is also used as a swaged needle ligature carrier on the ligature for incompetent cervix.

## OTHER NEEDLE FEATURES

### Anatomy of a Surgical Needle

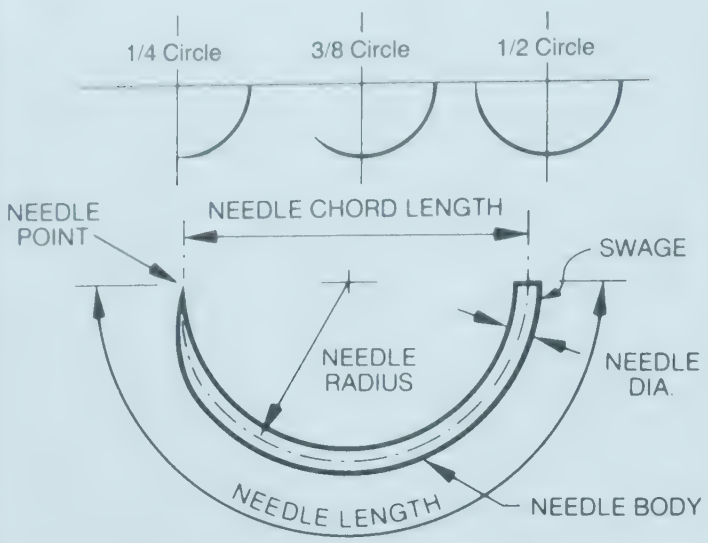
Surgical needles vary in size and wire gauge. *Fig. 22* shows the anatomy of a surgical needle.

CHORD LENGTH. Chord length is the straight line distance from the point of a curved needle to the swage. This can vary from 2 mm to more than two inches *(5.1 cm or 51 mm)*.

NEEDLE LENGTH. Needle length is the distance measured along the needle itself from point to end. Straight needles vary in length from 2 mm to 3½ inches *(8.9 cm or 89 mm)*. Curved needles vary from 2.5 mm to 3¾ inches *(9.5 cm or 95 mm)*.

4. Ibid, p. 92
*Trademark

Fig. 22 Anatomy of a surgical needle




RADIUS. If the curvature of the needle were continued to make a full circle, the radius of the curvature is the distance from the center of circle to the body of the needle. This varies from 1 mm to 1⅛ inches *(2.85 cm or 285 mm)*.

DIAMETER. The diameter is the gauge or thickness of the needle wire. This varies from 30 microns *(.001 inch)* to 56 mil *(.056 inch, 1.4 mm)*. Very small needles of fine gauge wire are needed for microsurgery. Large, heavy gauge needles are used to penetrate the sternum and to place retention sutures in the abdominal wall. A broad spectrum of sizes are available between these two extremes.

### Ribbed Needles

In 1964, ETHICON, INC., introduced a modification in needle design to virtually eliminate the undesirable problem of surgical needles rocking, twisting and turning in needleholders. Longitudinal ribbing or grooves on the inside or outside curvatures, or on both surfaces of curved needles provides a cross-locking action in the needleholder that gives unsurpassed needle control. The ribs are counter directional to serrations in the jaws of the needleholder, lending stability to its grasp. All ETHICON curved needles of 26 mil wire diameter or heavier are ribbed. Use of a ribbed needle permits a wider range of location for the needleholder without loss of stability. The ribs allow a needle to be placed securely in the needleholder at almost any angle for optimal maneuverability in various anatomic locations.

Fig. 23 Ribbed needle– an ETHICON exclusive

### Side-Flattened

Most curved needles are flattened in the needle grasping area to enhance control in the needleholder. The body of some needles also are side-flattened in an opposing direction. This increases strength by 12 percent, without increasing diameter. This process allows ETHICON to reduce the wire diameter of these needles, thereby improving the needle/suture ratio. The side-flattened needle allows the suture strand to fill the needle hole more easily than an oval or rectangular configuration *(see Fig. 24)*.

Fig. 24 Needle/suture ratio of ETHICON side-flattened needle


### Single- Versus Double-Arm

Usually the surgeon sutures with one needle swaged to the suture strand. This is referred to as a single-armed suture. Situations arise in practically every surgical specialty, however, when the surgeon wishes to place a suture and then continue to approximate surrounding tissue on both sides from a midpoint in the strand. In these situations, a double-armed suture is used. This is a suture strand with a needle swaged at each end. These needles are not necessarily the same size and shape.

## CHOOSING APPROPRIATE NEEDLES

"One basic assumption must be made in considering the ideal surgical needle for a given application, namely, that the tissue being sutured should be altered as little as possible by the needle since the only purpose of the needle is to introduce the suture

into the tissue for application." If the surgeon accepts this assumption, "the needle should be large enough and of appropriate shape and design to permit rapid, accurate and precise suturing, and the needle should be of such material and design as to minimize needle damage, breakage or alterations of its physical and architectural design."[5]

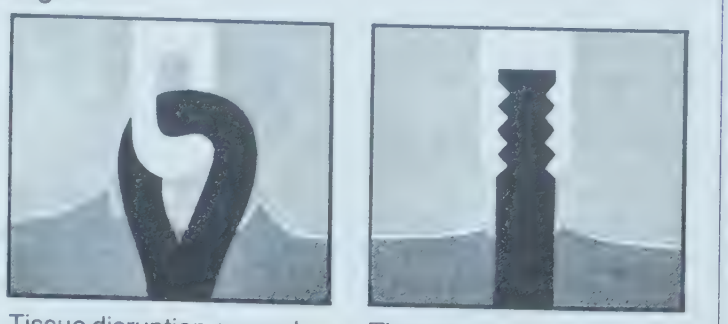
ETHICON stainless steel needles are manufactured to exact specifications. Over 150 needle designs are offered to the surgeon who usually selects the appropriate needle for the tissue/s to be sutured. While most surgeons have definite suture routines, a few do not specify needle preferences. The scrub nurse or surgical technologist may have to choose an appropriate needle. While no hard-and-fast rules govern needle selection in every circumstance, the scrub nurse may keep these basic principles in mind:

1) Try to match needle diameter to suture size, if using eyed needles. Swaged needles eliminate this concern.
2) Select the length, diameter and curvature by the size and depth of the area in which the surgeon is working. Watch the surgeon's progress closely.
3) Consider the tissue in which the surgeon will use the needle. Generally speaking, taper point needles are most often used to suture tissues that are easy to penetrate. Cutting or TAPERCUT needles are more often used in tough, hard-to-penetrate tissues. When in doubt about whether to choose a taper point or cutting needle, it is usually best to choose a taper point, except for skin sutures. Cutting needles are always used on the skin.
4) Consult with the surgeon. Working frequently with the same surgeon allows the scrub nurse to become familiar with his or her individual needle preferences. However, the same surgeon may need to change needle type or size to meet specific patient circumstances.
5) The best general rule for the scrub nurse to follow is to pay attention to the progress of the operation as much as possible. Use observation as a guide to needle selection if the surgeon's preferences are not made known.

## ADVANTAGES OF SWAGED SUTURES

Needles swaged to suture material are made of wire consistent in diameter to the size of the suture strands. Suture strands with eyeless needles attached offer several advantages to the surgeon, nurse and patient:

Fig. 25



Tissue disruption caused by double suture strand with eyed needle.

Tissue disruption minimized by single suture strand swaged to needle.

1) When the surgeon requests a particular suture by code number, a decision as to the type of needle need not be made during the operation since the proper needle is already attached to the preferred suture. The scrub nurse is relieved of the burden of needle selection when swaged sutures are used.
2) Minimal handling and preparation are required. The strand, with appropriate needle securely attached, is ready to be used as it comes from the packet. This helps maintain the integrity and strength of the suture due to minimal handling of the suture material.
3) Tissues are subject to less trauma from pulling through a single strand attached to a new, sharp needle. An eyed needle carrying a double strand creates a larger hole with additional tissue disruption *(see Fig. 25)*.
4) Tissue trauma is further reduced because a new, undamaged swaged needle is provided with each suture strand. The needle is discarded after use. Potentially dull or burred reusable needles are eliminated.
5) Swaged sutures eliminate threading at the operating table and do not unthread prematurely.
6) If a needle is accidentally dropped into a body cavity, recovery of the needle is facilitated by being attached to a suture strand. This is an important safeguard to prevent loss of a needle in a body cavity or orifice.
7) Inventory and time spent cleaning, sharpening and sterilizing reusable eyed needles can be reduced or eliminated by using swaged sutures. "When the expense of manufacturing swaged needles is compared with the cost of needle preparation and threading, swaged needles possess distinct advantages over eyed and reusable needles."[6]

5. Ibid, p. 89
6. Ibid, p. 89

8) CONTROL RELEASE needles allow placement of many sutures rapidly. This may reduce operating time for the surgeon, and ultimately the time the patient is anesthetized.
9) Quality and performance are consistent when the surgeon uses ATRALOC needles and/or CONTROL RELEASE needles.
10) Needles are free of corrosion.

## NEEDLE HANDLING TIPS

The scrub nurse should remember and observe the following in handling surgical needles:

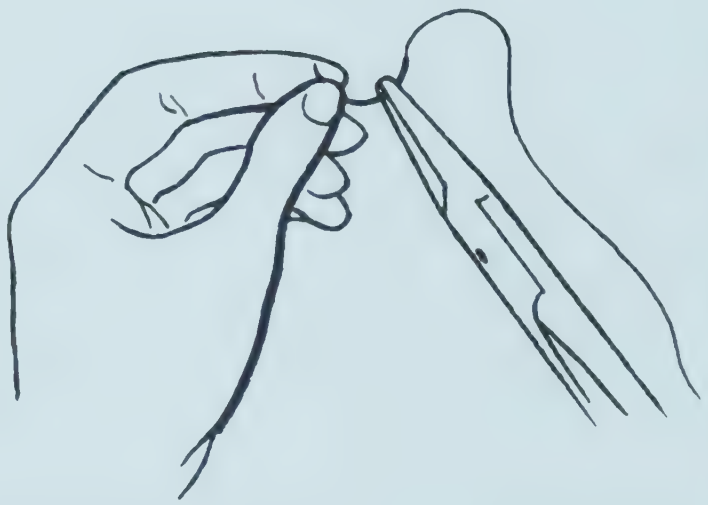
1) While opening packets and preparing sutures for the surgeon, the scrub nurse contributes to good patient care by protecting needle sharpness and suture strength. EASY ACCESS* packaging helps minimize handling of both the needle and suture. ATRALOC needles and CONTROL RELEASE needle sutures are prepared for use as illustrated in *Fig. 26*.
2) Always protect the needle to prevent dulling its point and cutting edges. These must be sharp and free of burrs. The needle also must be free of corrosion.
3) The scrub nurse must thread eyed needles at the operating table. Preparation of eyed needles is illustrated in *Fig. 27*.
4) Always inspect eyed needles to be certain they do not have rough or sharp edges inside the eye. Suture fraying and breakage can result from defective needle eyes. The point of each eyed needle should be checked for burrs or bluntness to insure easy penetration and passage through tissue. When a defect is noted, the needle must be discarded.
5) All needles must be counted before and after use, according to hospital procedure. The scrub nurse should retain the packet with descriptive information of number and type of needles to help determine if the count is correct for swaged and disposable needles. Used needles must be secured until after the final count. The following are methods for efficient handling during the operation.
   a. Sterile adhesive pads with or without magnets or disposable magnetic pads facilitate counting and safe disposal.

*Trademark

**Fig. 26 Preparation of swaged suture**

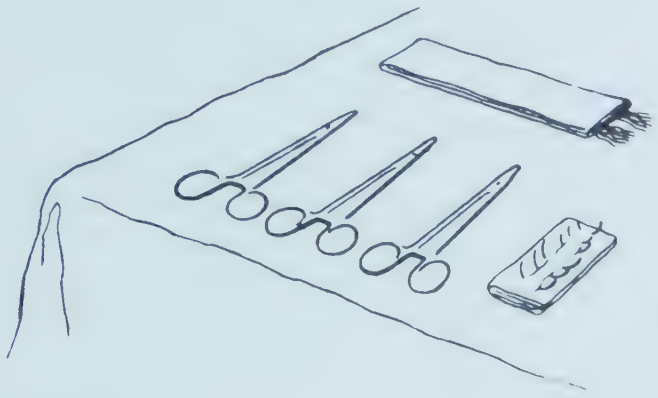

1. Tear open foil packet. Remove strand from protective folder.

2. If necessary to straighten, grasp strand 1″-2″ away from needle-suture junction and pull gently.

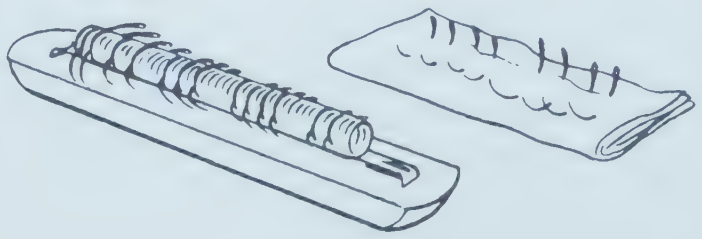


3. Clamp needleholder about ¾ of distance from needle point. Do not clamp at swaged area. Place needle near tip of holder to facilitate suturing.

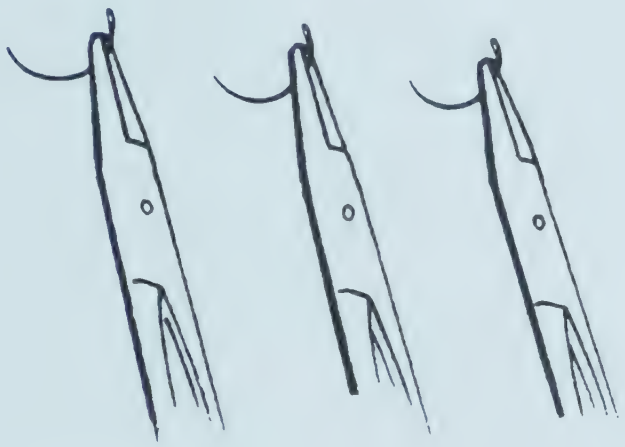
**Fig. 27 Preparation of eyed needle sutures**



1. Store cut lengths of suture material in folds of dry towel ("suture book") and place in suture preparation area of sterile supply table.



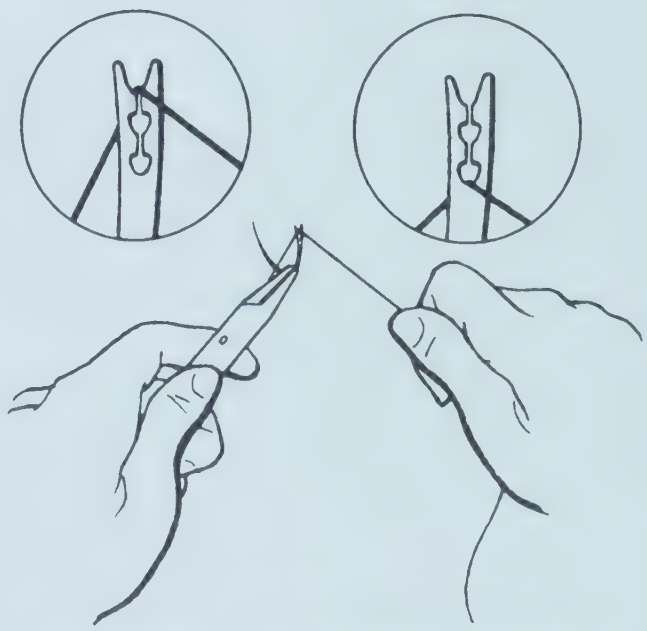
2. From metal springholder or "needle book" select 2 or 3 eyed needles of one size and type (surgeon preference). Inspect needles for burred points, eye defects and corrosion.



3. Place eyed needles on needleholders of appropriate length. Clamp holder approximately ¾ of distance from point to eyed end of needle. Clamp needle near tip of holder.

4. If threading from inside curve of needle, as is often taught, avoid puncturing glove with point of needle. Unless strand is limp, it may be easier to place needle eye over end of strand than to thread in the conventional manner.

5. Pull short end of strand 2″-3″ through needle eye. For deep suturing, make the short end about 4″ long.



6. To thread French eye (split eye or spring eye) needle, secure short end of strand between fingers of left hand holding needleholder. Pull strand taut across center of V-shaped area above eye. Strand will spring into eye through slit. (Note: French eye needles are easily broken. Check to see that eye is intact before threading.)

b. Swaged needles can be inserted through or into their original packet after use. An empty packet indicates a missing needle.
c. Eyed needles should be returned to the needle rack, or threaded into the top layer of the suture book.
d. Accumulation of used needles in a medicine cup or other container is the least desirable method because each must be handled individually to count them. This not only potentially contaminates gloves, but may puncture them as well.[7]

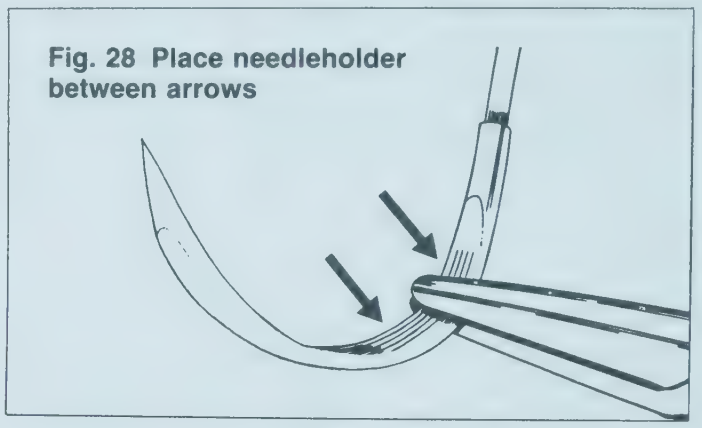
6) Pass needles to the surgeon on an exchange basis; one is returned before another is passed. Secure each needle as soon as the surgeon has used it. Needles should not lie loose on the sterile field or Mayo stand. They should be kept away from sponges and tapes so they will not be inadvertently dragged into the wound.
7) If a needle breaks, all pieces must be accounted for.
8) If eyed needles are reused, they must be cleaned and reprocessed at the end of the operation. Swaged and disposable needles are discarded after the final count.

## SELECTION OF NEEDLEHOLDERS

A needleholder is the instrument used by the surgeon to pass a curved needle through tissue. It must be made of noncorrosive, high strength, good quality steel alloy with the jaws designed for security of needles. The jaws of some needleholders have diamond-cut surfaces. Others have a tungsten carbide insert to increase hardness of the jaws. The jaws may be short or long, broad or narrow, slotted or flat, concave or convex, smooth or serrated. Most, but not all, needleholders have a ratchet lock distal to thumb and finger rings.

The scrub nurse secures the needle in the needleholder before handing it to the surgeon as shown in *Fig. 29*. Correct arming of the needle and passing of the needleholder save time for the surgeon. More importantly, to prevent injury to the patient:

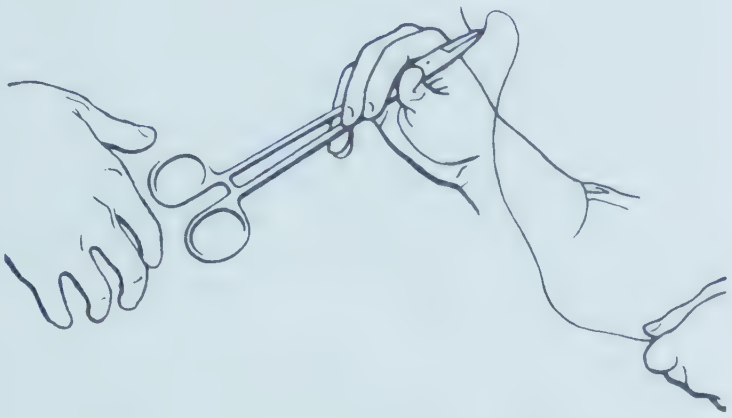
1) Always use an appropriate needleholder for the size of the needle. Extremely small needles require a needleholder with a tip of consistent fineness. The larger and heavier the needle, the wider and heavier the jaws of the needleholder should be. As the surgeon works deeper inside the abdomen, chest or pelvis, a longer needleholder will be needed. "Choice of a particular size and type of needleholder should be determined by the characteristics of the needle to be held and the wound or anatomic area in which suturing is to be accomplished."[8]
2) Always place the needleholder away from the swage or eye of the needle. Needles should be grasped in an area about ¼ to ½ of the distance from the swaged area to the point as shown in *Fig. 28*. Avoid placement on or near the swaged area.




3) Always check alignment of the needleholder jaws. "The tips of the jaws should meet before the remaining portions of the jaws come together to assure the most positive grasp of a needle."[9] The needle should be placed securely in the tip of the jaws. It should not rock, twist or turn. It should feel stable in the needleholder.
4) Always close the needleholder on the first or second ratchet. If the needle is held too tightly in a sharp, hard jawed or a defective needleholder, the needle may be damaged or notched in such a manner that it will have more of a tendency to bend or break on successive passes through tissue.
5) Always pass the needleholder so that the needle point is directed toward the surgeon's thumb. The needle will be pointing in the direction to use it without need for readjustment.
6) Always pass the needleholder to the surgeon so that the suture strand is free and not entangled with the needleholder. If the strand is long, protect the end from dragging across the sterile field by holding it in one hand while passing the needleholder with the other.
7) Always hand the surgeon's assistant a needleholder to pull the needle out through the tis-

7. Atkinson LJ, Kohn ML: *Berry and Kohn's Introduction to Operating Room Technique*, 5th ed, New York: McGraw-Hill, 1978, p. 153
8. Trier: op cit, p. 93
9. Ibid

**Fig. 29 Placement of needle in tissue**



1. Surgeon receives needleholder with needle point toward his thumb to prevent unnecessary wrist motion. Scrub nurse controls free end of suture to prevent dragging across sterile field.

2. Surgeon begins closing with swaged suture.

3. Needle is passed into tissue. Surgeon releases needle from holder and reclamps holder near point end to pull needle and strand through tissue. Eyed or CONTROL RELEASE* needle is released from suture.

4. Surgeon leaves CONTROL RELEASE needle or empty eyed needle clamped in same position and returns it to nurse. She passes another prepared suture to him immediately. (Note: Keeping up with needles is easiest if done on a "one-for-one" basis.)

*Trademark

sue. *Only a needleholder,* never a hemostat, is used for this purpose. A hemostat or other clamp can damage the needle.

8) Always try to avoid puncturing gloves when handling or passing needles. If a glove is punctured, it must be changed immediately and the needle discarded.
9) Always use needles and needleholders as a unit. "Some hospitals go by the rule: no needle on the Mayo stand without a needleholder and no needleholder without a needle."[10]

## PLACEMENT OF NEEDLE IN TISSUE

A surgical needle is an instrument that complements the surgeon's skills. Most swaged needles have a SUPER-SMOOTH finish that permits the needle to penetrate and pass through tissue with minimal resistance or drag. The longitudinal ribs in many of the needles manufactured by ETHICON, INC., increase stability of these needles in the needleholder. The surgeon, however, must use the appropriate instruments correctly for every surgical requirement. While suturing, improper technic may result in needle breakage. Some precautions to remember when placing a needle in tissue include:

1) Any force should be applied in the direction following the curvature of the needle.
2) Do not take excessively large bites of tissue with an inadequately small needle.
3) Do not force a dull needle through tissue. Get a new one.
4) Avoid using the needle to bridge or approximate tissues for suturing.
5) Grasp the needle with the needleholder approximately ¼ to ½ of the length of the needle from the swaged end. Do not grasp on the swage. This is the weakest part of the needle. While needle breakage is a rare occurrence, improper placement of the needle in the needleholder may result in a broken portion that could mistakenly be left in the patient.
6) Do not force or twist the needle in an effort to bring the point out through the tissue. Withdraw the needle and replace it in tissue, or use a larger needle.
7) Do not damage taper points or cutting edges when using the needleholder to pull the needle through the tissue. The needle should not be grasped on the point. The point and swaged portion are slightly weaker than the body of the needle. Grasp as far back on the body as possible.
8) In an individual patient, the tissue may be tougher or fibrosed more than normal and require the use of a heavier gauge needle. Conversely, a smaller needle may be needed for tissue more friable than normal.
9) In a deep confined area, ideal positioning of the needle may not be possible. The surgeon should proceed with caution. A heavier gauge needle or a different curvature may be indicated.
10) Immediately after use, every needle should be returned to the scrub nurse clamped in the needleholder. Prevention of loss of needles is easiest if they are passed on a "one-for-one" basis, i.e., one returned for each one received. *(See Fig. 29.)*
11) If a needle breaks, every effort should be made to retrieve all portions. Likewise, the wound should be explored if the final needle count is incorrect.

10. Atkinson LJ, Kohn ML: op cit, p. 153

SECTION VI

# Mechanical Wound Closure Devices

Except for improvements in material quality, suturing of the wound has changed little since the first operative procedure. However, the emergence of a different approach to wound closure is changing some operative technics. It can provide surgeons the opportunity to save significant time under anesthesia for some patients. Secure and surgically acceptable closures can be obtained. Tissue trauma is reduced in some procedures, and the cosmetic appearance following healing can be improved in others. Providing the force behind these and other benefits is the use of mechanical ligating and wound closing devices. These mechanical devices involve the use of *clips* or *staples* together with a corresponding instrument to apply them.

## LIGATING CLIPS

Until the early part of the twentieth century, ligatures and cautery were the sole methods of controlling bleeding from severed vessels. Then, in 1908, Dr. Harvey Cushing developed a device to control bleeding. This small U-shaped piece of silver wire was held in the jaws of a hemostat, attached to the vessel and cut. The resulting wire clips were of various sizes.

Dr. Cushing's original method was improved through the development, by Dr. F.G. McKenzie of Toronto in 1927, of a clip-forming forceps which simultaneously cut the silver wire and formed the clip with one action. This resulted in uniform clips that could be made rapidly. Dr. McKenzie also substituted flattened wire for the rounded wire of Dr. Cushing, which eliminated the tendency of the clip to twist and fall from the applier. These clips gained wide acceptance among neurosurgeons.

Silver wire continued to be used even though an extensive inflammatory reaction appeared in the surrounding tissue. In 1942, tantalum was substituted for the silver. It produces appreciably less foreign body reaction.

In the early 1960s, Dr. Peter Samuels developed a new hemostatic clip designed to speed the use of clips for vessel ligation. Since that time, the use of ligating clips has expanded to include general, cardiovascular, thoracic, urologic and gynecologic, as well as neurosurgeons.

Ligating clips afford the surgeon a rapid and secure method of accomplishing hemostasis or ligating arteries, veins, nerves and other small structures. Ligating clips can be used for the permanent occlusion of major vessels in deep, confined areas where the surgeon may encounter poor visualization. They also may be used in lieu of free suture ties or stick ties for many vessels or structures under direct vision in areas where rapid control of bleeding is indicated. They are especially advantageous in deep, difficult to reach areas. Overall, clips afford speed, efficiency and reliability where rapid control of bleeding is required.

In 1973, ETHICON, INC., took a significant step into the total wound closure business with entry into the mechanical instrumentation field with LIGACLIP* ligating clips and appliers. In 1980, stainless steel ligating clips were introduced in addition to the tantalum clips already available. And in 1982, absorbable ligating clips were introduced and titanium clips in 1984.

### Nonabsorbable Ligating Clips

LIGACLIP ligating clips are produced from 316L stainless steel, tantalum or titanium. These materials do not elicit gross tissue reaction following implantation. The clips are designed for ligation of tubular structures wherever, in the surgeon's opinion, a *nonabsorable* ligating device is indicated. Unlike electrocoagulation, the vessel and/or tissue is occluded without thermal destruction. Because metallic clips are radiopaque, they may be used to mark internal structures for postoperative x-ray identification. However, titanium produces less artifact *(distortion and flares)* than stainless steel and tantalum when subjected to CT scans. All the clips are nonmagnetic.

Ligating clips are positioned around a tubular structure and closed by applying pressure on handles of the applier. Tantalum clips are heavier than stainless steel clips, and therefore have a slightly different feel. The tantalum clips have a duller, nonreflective finish that some surgeons prefer. The titanium clips have a dull blue finish to differentiate them from the other metals. LIGACLIP ligating clips are supplied in sterile cartridges, each color coded by size, in use-oriented multiples of six per cartridge. A weighted cartridge base is available to stabilize clip cartridges for loading and quick identification of correct clip size.

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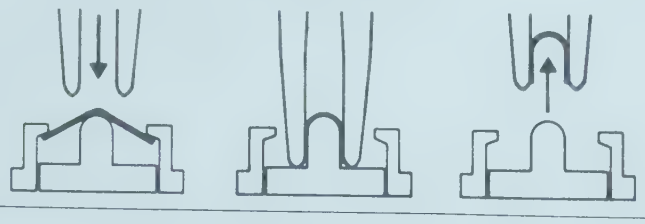
LIGACLIP appliers are designed for use specifically with LIGACLIP clips. Other appliers should not be used. Condition of the applier, closure force exerted by surgeon, thickness of tissue to be ligated, and nature of the clip itself are all critical to performance of any ligating clip. The appliers are made of stainless steel. The ring handles are color coded to match the clip cartridges. This enables fast and accurate selection of applier to be used with each size clip. Appliers in disrepair should not be used. They should be returned to ETHICON, INC., for repair or replacement. Use of such appliers could result in inadequate function of a clip.

LIGACLIP clips and appliers should be used as follows:

1) Based upon the experience of the surgeon, select the appropriate size ligating clip and corresponding applier to be consistent with the diameter of the tubular structure being ligated. Four sizes of clips and appliers are available: small, medium, medium-large and large. The appliers are available in a variety of shapes to accommodate the numerous conditions encountered by the surgeon.
2) To load, grasp applier in box lock area using pencil grip technic. The applier opens to a precise tolerance when grasping the clip.
3) Insert jaws of instrument into individual cartridge slot making sure the tips of the applier are perpendicular to the surface of the cartridge. Applier should be inserted until it stops. There is no need to force the applier. It should enter and withdraw from the cartridge smoothly. *(See Fig. 30.)*

**Fig. 30 Loading clip in applier**



4) Retract the applier from the cartridge. Clips are formed as they are loaded into the applier and locked in the jaws by the cross-locking action between serrations in the clip and the applier. The clip will be securely held in the applier jaws. It is not necessary to maintain ring tension to hold the clip in the applier jaws.
5) The applier, with the clip in the jaws, is ready to be passed to the surgeon. The applier can be transferred from hand-to-hand without the scrub nurse and surgeon grasping the handles to maintain pressure.

In contrast to the individually loaded appliers, LIGACLIP* MCA multiple clip appliers contain a choice of either 20 or 30 medium-size preloaded stainless steel ligating clips. This sterile, disposable instrument is designed to offer surgeon a rapid, efficient means of ligation. After placing one clip, the next clip is positioned automatically in the instrument jaws for the next ligation. With a one-hand, single motion to close ring handles, each clip is applied. The angle of the applier jaw allows a direct line of vision to ligation site.

To ligate the desired tissue/vessel with the LIGACLIP MCA or LIGACLIP applier with single clip in the jaws:

1) Position clip around the tubular structure to be ligated. The applier and clips are designed to provide accurate alignment virtually eliminating twisting and slipping.
2) Close applier by applying pressure to the handles. The surgeon should apply sufficient force to close the applier to assure that the clip is satisfactorily placed. The clip closes distally before the entire clip closes down. This assures that the vessel will not slide away before closure is complete.
3) Open applier by relieving the closing force. Smoothly withdraw it from the ligation site when the jaws are fully open. The clip has small serrations on the inner surfaces to keep it from slipping when placed on a vessel.

Multiple clips may be placed as dictated by the experience and judgment of the surgeon. Working with pairs of single clip appliers or a multiple clip applier facilitates transfers from scrub nurse to surgeon with minimal delay.

As with any ligating method, the surgeon should inspect each ligation site following placement of the clip to insure that the clip has been satisfactorily placed. If the surgeon deems it advisable to remove a clip, the LIGACLIP* clip remover is designed specifically for this purpose. When applied, the remover spreads the clip open. It is then backed off without damaging the vessel.

### Absorbable Ligating Clips

ABSOLOK* ligating clips are molded from the polyester poly *(p-dioxanone)*. Dyed violet, polydioxanone absorbable clips are sterile, nonantigenic, nonpyrogenic, and elicit only a slight tissue response during absorption. The general mech-

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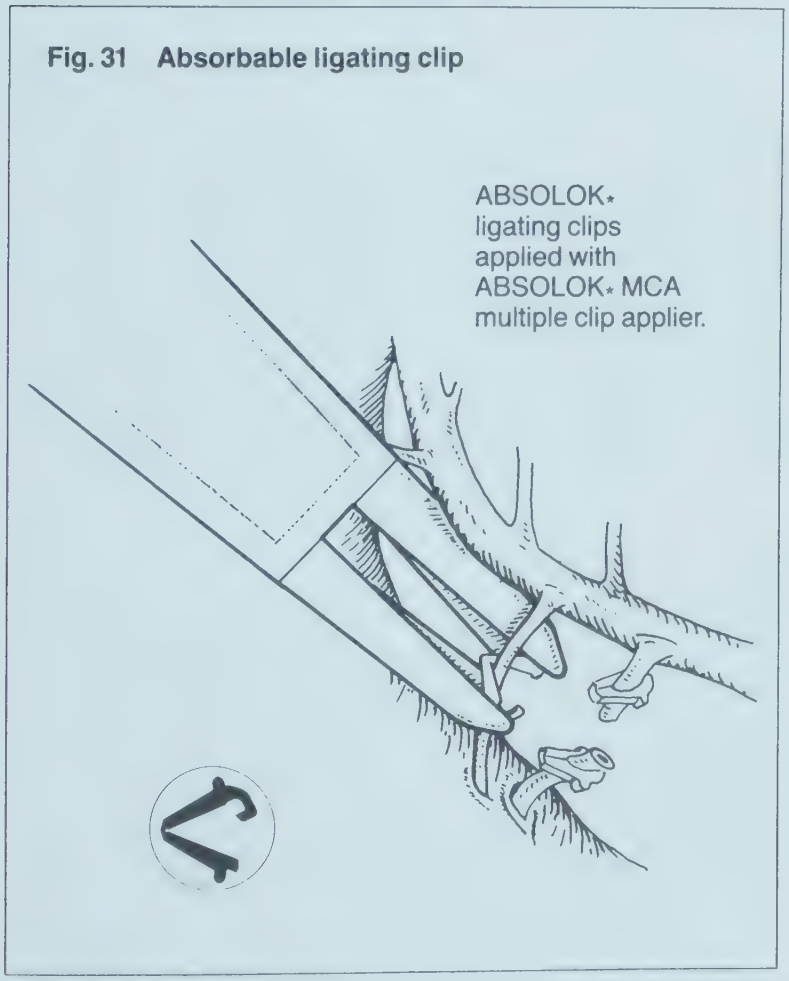
anism by which *in vivo* degradation of polydioxanone occurs is hydrolysis. The *in vivo* hydrolysis of polydioxanone cleaves the ester linkages and initially results in the loss of strength. Ultimately, the hydrolyzed polymer is eliminated from the body, primarily in urine. The absorption of these clips is minimal until about the 90th post-implantation day. Absorption is essentially complete within 210 days.

ABSOLOK clips are intended for use as *absorbable* ligatures. These clips are designed to offer a rapid, efficient means of ligation. They retain their strength longer than necessary for a thrombus or clot to occur in a vessel. Unlike conventional hemostatic clips, the absorbable clips are radiotransparent. Therefore, they will not interfere with interpretations of postoperative x-ray and/or CT scans. Absorbable clips should not be used where prolonged or permanent ligation of tissues or vessels is required. The safety and effectiveness of this clip in the vas deferens has not been established.

The clip is comprised of two legs joined at the proximal ends forming a resilient hinge. The first leg terminates in a deflectable latch adapted to engage securely the distal end of the second leg *(see Fig. 31)*. In closing, the hinge flexes until the distal end of the second leg bypasses and locks under the latch of the first leg. The clip must be latched to insure proper ligation of the vessel or tissue.

**Fig. 31 Absorbable ligating clip**

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The ABSOLOK* ligating clip applier, designed for use specifically with ABSOLOK ligating clips, facilitates access to virtually all vessels and/or tissues. Only this applier of the appropriate size should be used. Other appliers can be used only if specifically designed for use with these clips. The clips should be applied as follows:

1) Based upon the experience of the surgeon, select the appropriate size clip and the corresponding applier to be consistent with the diameter of the vessel being ligated.
2) Grasp applier in box lock area using pencil grip technic.
3) Insert jaws of instrument into individual cartridge slot, making sure the tips of the applier are perpendicular to the surface of the cartridge. Applier should be inserted until it stops. There is no need to force the instrument. It should enter and withdraw from the cartridge smoothly.
4) Retract applier from cartridge. The clip will be securely held in the applier jaws. There is no need to maintain ring tension since the clip is locked in the jaws.
5) The applier, with the clip in the jaws, is ready to be passed to the surgeon and ready to ligate the desired tissue/vessel.
6) The clip is applied by closing the instrument until there is tactile locking response or the opposing jaws are nearly flush. The INTERLOCK* locking feature will securely hold the clip on the desired tissue or vessel. The instrument is opened by relieving the closing force and can be smoothly withdrawn from the ligation site when fully opened.
7) Multiple clips may be placed as dictated by the experience and judgment of the surgeon.

The ready to use sterile, color coded cartridges of ten clips each, are easily matched to appliers correspondingly color coded by size. Do not resterilize the clips or clip cartridges.

In addition to the single clip ligating system, ABSOLOK* multiple clip appliers offer the surgeon the convenience and speed of multiple ligations without interruption. The ABSOLOK MCA is supplied preloaded with either 20 or 30 polydioxanone absorbable ligating clips. This applier is supplied sterile and is disposable after use. The curved jaws of the applier provide excellent visibility of the ligation site. The clips should be applied as follows:

1) Based upon the experience of the surgeon, the size of the clip should be consistent with the size of the tissue structure being ligated.

2) The applier may be grasped in the conventional manner for ring-handled instruments.
3) Position the clip around the structure to be ligated, making certain tissue will not interfere with the clip latch. The clip is applied by closing the instrument until the operator feels the applier reach the stopping point.
4) The applier is opened by relieving the closing force.
5) Care should be taken to open the applier while simultaneously backing away from the ligation site. This will ensure that the closed clip does not interfere with the smooth advancement of the next clip.
6) When the instrument has been cycled through its entire sequence, the next clip will be properly positioned in the jaws.
7) After the last clip has been used, the applier will lock in an open-jaw configuration to prevent applying empty jaws to tissue.

As with any ligating device, the surgeon should inspect the ligation site following placement of the clip to insure that proper hemostasis has been achieved. The vessel must be freed up 360 degrees *(isolated)* so the clip latches properly. The latching mechanics of the clip include an audible and tactile snap which assures that adequate ligation of the vessel or tissue has occurred. Failure to realize the snap usually is due to attempting to ligate too much tissue with the clip. This results in the failure of the absorbable clips to close and is immediately recognized as a failure to ligate.[1]

## SURGICAL STAPLES

Beginning with the early days of surgery, surgeons were concerned about the amount of time required and the extent of tissue trauma inflicted to perform certain procedures. Although many attempts were made to reduce these hazards, it was not until 1908 that the first mechanical wound closure device for internal use was acclaimed by a Hungarian surgeon, Professor Hamer Hültl of Budapest. This instrument was used to place straight double rows of staples in an alternating fashion across the stomach. Hültl recognized the importance of two principles: the need for a B-shaped formation of the staples and fine wire as the basic staple material.[2]

Then in 1924, also in Hungary, Aladar von Petz developed a mechanical device for gastrointestinal anastomosis. Silver staples were individually inserted in two parallel rows along the jaws of this cumbersome clamp which weighed over seven pounds. The von Petz clamp received worldwide acceptance even though it was difficult to prepare and use. It did reduce operating time and tissue trauma.

Since these beginnings, other developmental milestones have occurred. In 1934 the first stapling instrument featuring a replaceable, preloaded staple cartridge was introduced by Dr. H. Friedrich of Ulm, Germany. However, it was used only for temporary closures. After being stapled, the tissue had to be inverted and secured with sutures.

The next milestone occurred in 1951 when a stapling instrument for use in vascular surgery was developed in Russia at the Scientific Research Institute for Experimental Surgical Apparatus and Instruments in Moscow. The Russians subsequently became the leaders in the field of stapling tissue. Most of the reusable staplers are available because of patents licensed from the Soviet Union. In 1967, one of these licenses led to the introduction in the United States of stapling instruments using disposable staple loading units. Each instrument is designed for stapling specific tissues, i.e., skin, fascia, bronchus, gastrointestinal tract, vessels, etc. The surgeon selects the correct instrument for the desired application.

In 1978, ETHICON, INC., introduced the world's first preassembled *disposable* stapling instrument. This was the PROXIMATE* disposable skin stapler. Then in 1980, ETHICON, INC., made available the PROXIMATE* ILS disposable intraluminal stapler for anastomoses in the alimentary tract.

Stapling offers some significant advantages over traditional suturing technics. It is faster and, hence, can reduce operating time. Trauma to tissue is reduced because tissue handling is minimized.

### Skin Staples

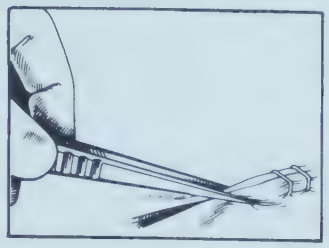
To understand the advantages of skin staples, it is necessary to keep in mind specific aspects of skin closure. Unless the tissues are brought together in precise approximation, complications in healing can interfere with desired cosmetic results. The two basic requirements for apposing skin are that:

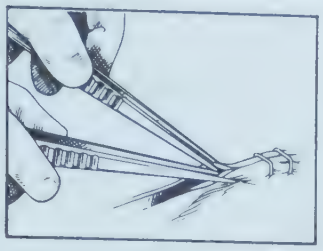
1) The edges of the cuticular and subcuticular layers are *everted*, that is, aligned with the edges slightly raised in an outward direction. As it heals, the tissue will tend to flatten out and form an even surface.

1. Schaefer CJ et al: Absorbable ligating clips, *Surg Gynecol Obstet 154:* 513-516, April 1982
2. Steichen FM: Staplers in intestinal surgery, *Contemporary Surg 14:* 51, June 1979

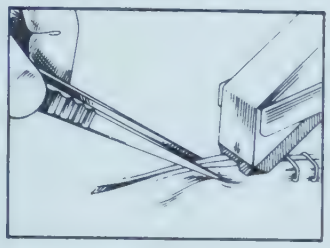
*Trademark

**Fig. 32 PROXIMATE* skin staplers**

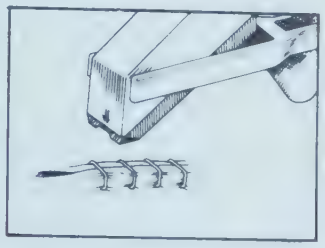




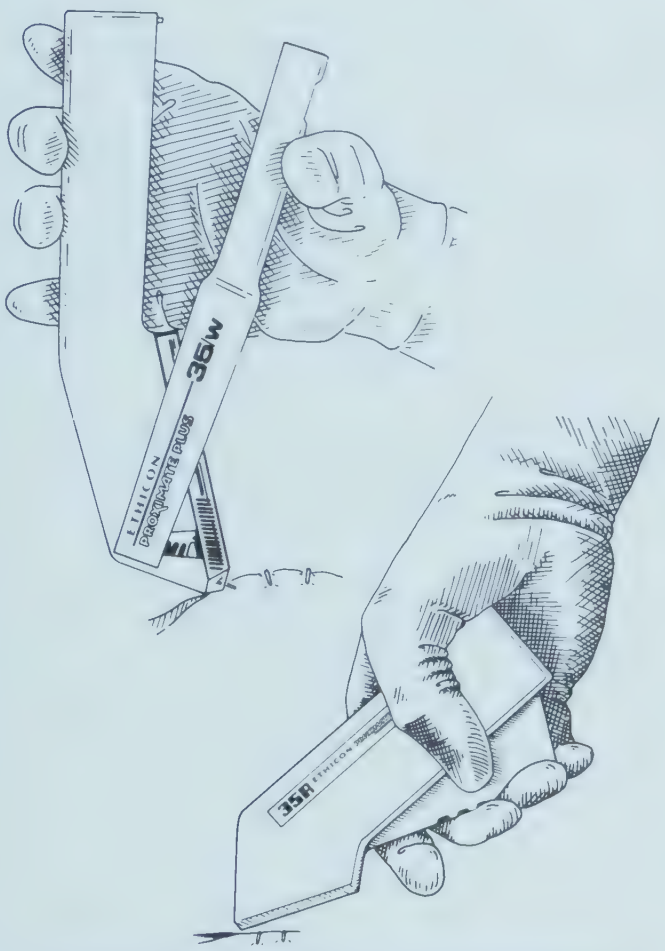
1. Evert and approximate skin edges as desired with one or two tissue forceps.



2. Position stapler very lightly over everted skin edges and squeeze trigger.



3. Back stapler off the staple.




4. Both stapler configurations can be fired from any angle.

2) The skin edges must be aligned as close to their original configuration on the horizontal plane as possible. If one edge is allowed to slide or to be placed in a location other than its original one, the best cosmetic results will not be obtained and unnecessary scars can form.

Several technics are used to evert and approximate skin edges prior to placement of staples *(see Fig. 32)*.

1) With one tissue forcep, force skin edges together until edges evert.
2) With two tissue forceps, pick up each wound edge individually and approximate the edges.
3) Apply tension to either end of the incision, such that the tissue edges begin to approximate themselves. One forcep can be used to insure that the edges are everted.

The staples are gently placed across the junction of the skin edges so they uniformly span the incision line. PROXIMATE skin staples, made of inert 316L stainless steel, are virtually nonreactive in tissue. The rectangular design minimizes tissue trauma and tends to minimize staple rotation after it is placed. Approximation of the skin edges by stapling minimizes tissue compression. The space between the staple crown *(top)* and the skin surface minimizes crosshatching marks so often associated with incisions closed with too much tension on a suture line or because of postoperative edema.

Skin staples are flexible in terms of their application. They can be used virtually anywhere, regardless of the contour of the body. They may be employed for routine skin closure in a wide variety of operative procedures, to secure skin grafts on burn patients, and for lacerations closed in the emergency department. When it is not possible to maintain at least 5 mm from the stapled skin to underlying bones, vessels or internal organs, the use of staples for skin closure is contraindicated.

The staples are totally self-contained in a cartridge within the stapler ready for firing. An arrow on the nose of the stapler over the tissue channel indentation in the cartridge orients the operator for centering the staple over the everted skin edges. Different configurations of sterile, disposable, lightweight instruments are available from ETHICON, INC.

The PROXIMATE* PLUS skin stapler *(see Fig. 32)*, is supplied preloaded with 15, 25, 35 or 55 regular or wide staples. The wire diameter of regular staples is .53 mm. They have a crown span of 5.7 mm. The wire diameter of wide staples is .58 mm and the crown span is 6.9 mm. Both sizes have a 3.9 mm leg. The different lengths of the crowns enable the surgeon to vary the span of the staples just as can be done with sutures.

The length of the incision to be closed also dictates the most appropriate stapler to be used. The

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exact number and the type of staples in each stapler are specified by the instrument designation on the side of the stapler and the *staple-left scale* on the bottom of the cartridge. Studies done prior to the introduction of a disposable skin stapler showed an average range of 28 and 35 staples were used for the majority of operative procedures. The 35 count staplers are used in closing incisions of at least five inches in length.

The PROXIMATE* II skin stapler has a different configuration *(see Fig. 32)*, and is available in staple counts of 15, 25 and 35. The formed staple dimensions are the same as the wide staples previously described. The compact size was engineered for natural fit and grip in the hand and for ease of maneuverability, versatility and control. The nose of the stapler must be held up with the tissue channel perpendicular to the skin.

Misfiring or jamming of PROXIMATE PLUS stapler and PROXIMATE II stapler can occur if the instruments are not used properly. They are designed to fire with one continuous motion. Therefore, precocking could result in jamming or misfired staples.

All the PROXIMATE skin staplers are constructed of a high quality medical grade plastic that enhances consistent molding. The other basic material used in construction of these instruments is stainless steel. They are lightweight, only a few ounces, and require less than ten pounds of force to fire. They can be fired from any hand-held position from the normal horizontal position to vertical or at an angle *(see Fig. 32)*.

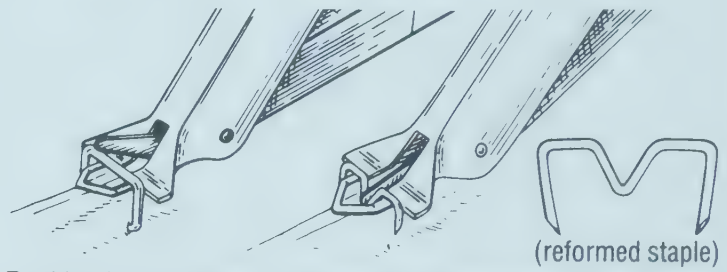
Staple placement is the same with all styles of staplers *(see Fig. 32)*.

1) Position the instrument very lightly over the everted skin edges, aligning the arrow on the nose with the incision to assure that the staple will centrally span the incision line. Pressing down on the instrument too heavily may make staple removable difficult.
2) Squeeze the trigger until the trigger motion is halted. As firing commences, the staple is forced against the anvil located in the nose. This action gradually bends the staple, causes it to enter the skin edges, and to assume its final rectangular configuration.
3) Release the trigger and back the instrument off the staple. By moving backward, the anvil easily slides out from under the staple. Backing the instrument off the staple allows the surgeon to inspect the previously fired staples prior to continuing the closure.

Staples must be removed postoperatively with an extractor designed for this purpose. The surgeon begins by sliding the lower jaw of the PROXIMATE* disposable skin staple extractor beneath the staple span. The lower jaw contains a slot that will securely hold the staple during extraction. The jaw must be positioned so that the staple rests in the slot. The surgeon then squeezes the extractor handles until fully closed. This action reforms the staple almost into its original shape with the legs parallel and withdraws it from the skin. The staple is lifted from the tissue.

Two different styles of PROXIMATE extractors are available. One has smooth handles; the other is a ring-handled instrument. The ring-handled style also has an angled flange (*wing*) on each side of the lower jaw that allows the jaw to be placed firmly on the skin surface to stabilize the extractor during staple removal. *(Fig. 33.)*

**Fig. 33 Staple removal: same with both styles of extractors**




All PROXIMATE skin stapler products are supplied sterile in blister peel-apart packets. Sterility is guaranteed unless the package is opened or damaged. The instruments should not be resterilized. They are single patient use instruments to be disposed after use.

### Intraluminal Staples

The PROXIMATE* ILS disposable intraluminal stapler system was designed for anastomosis of the tubular, hollow organs of the alimentary tract. This type of procedure generally involves resecting a diseased segment of an organ and anastomosing the organ to restore continuity of the tract. When a hollow organ such as the bowel is resected, the lumen of both segments is relatively circular. The first modern stapling instruments placed staples in straight rows. While they could be used to anastomose hollow organs, the round staple cartridge of

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the ILS stapler places a double row of staggered staples that most closely approximates the shape of the organ and allows it to function effectively. The tissue is inverted.

When used correctly, the stapler enables the surgeon to adhere to the four basic principles of anastomosis.

1) Preservation of blood supply. The surgeon must be careful not to compromise the blood supply to the tissue at and around the anastomotic site. If this occurs, the tissue can necrose and slough, causing a defect in the anastomosis. This defect might allow leakage to occur. Infection could result.
2) Prevention of tension. The organ must not be taut and under tension at the anastomotic site.
3) Minimize trauma to tissue. The less tissue is handled, the greater the possibility of healing. Surgeons avoid handling tissue whenever possible.
4) Leak-proof closure. Before closing any abdominal incision, the surgeon must check for seepage of blood or serum around the anastomosis. Any leakage can result in gross postoperative pain and infection.

The ILS staplers have application for inverted end-to-end, end-to-side and side-to-side anastomoses throughout the alimentary tract from the esophagus to the rectum. Except in a low anterior resection when entry through the dilated anus is feasible, the stapler is introduced through an enterotomy or gastrotomy site. The use of the stapler is contraindicated in ischemic or necrotic tissue.

The ILS staplers are fabricated from a combination of lightweight alloys and plastic components. Four sizes are available to permit proper matching of instrument to diameter of the lumen of the organ/s to be anastomosed. The diameter of the lumen varies throughout the alimentary tract. For example, the esophagus is typically between 21 and 25 mm, the small intestine between 21 and 30 mm, and the large intestine between 25 and 33 mm. The outside diameters of the heads of the four sizes of staplers are 21, 25, 29 and 33 mm. If the internal diameter of the tubular structure is less than 21 mm, the use of the ILS stapler is contraindicated.

Staple height is adjustable to compensate for varying tissue thickness. Just as the diameter of the lumen varies, so does the thickness of organs. For example, the esophagus, duodenum and jejunum are typically about 1.8 mm in thickness. The ileum is 1.3 mm. The large intestine varies from 1.9 to 2.8 mm, and in some patients may reach 4.0 mm. The stapler permits variations in gapsettings ranging from 1.0 mm to 3.0 mm, depending on the thickness of tissues being anastomosed. Any gapsetting within this range ensures a circle of properly formed staples. "This design feature offers the advantage of reducing possible trauma to the intestine by compression between anvil and cartridge during the stapling process."[3] Where the combined tissue thickness requires an instrument setting of less than 1.0 or greater than 3.0, the use of the ILS stapler is contraindicated.

To select a stapler of the proper size, the organ diameters must be measured at the two anastomotic sites. The PROXIMATE* TMD disposable tissue measuring device is used for this purpose. *(See Fig. 34.)* The measurement on the *organ diameter scale* indicates the size stapler that should be used. This caliper-like device also measures the thickness of tissue of both segments to determine the appropriate setting for the gap on the stapler. *(See Fig. 34.)* An improper adjustment of this gap can result in the staples forming to the wrong dimension, thereby jeopardizing the integrity of the anastomosis. By setting the gap, the closed staples maintain 8 grams per square mm of pressure. This is the average pressure point for normal hemostasis and to prevent leakage. For the surgeon's initial experience with the ILS system, it is recommended that the tissue measuring device be used in conjunction with the ILS stapler to achieve a proper anastomosis. "After some experience, the surgeon may be able to independently determine a clinical estimate of the tissue thickness and appropriate instrument setting."[4]

Prior to insertion of the ILS stapler through an enterotomy or gastrotomy incision or through the anus for low colon anastomosis, purse-string sutures are placed in the segments of the organs to be anastomosed. These sutures may be placed using the PROXIMATE* PSD disposable purse string device or by a manual technic. In the event that a manual technic is selected, a through-and-through technic is suggested. Whip-stitching *(over-and-over)* is not recommended. The purse string device facilitates placement of the purse-string sutures. Use of this device insures that an adequate, minimal cuff of tissue is available for securing to the center rod of the stapler. The lightweight self-locking, hinged device is placed across the tubular structure to be anastomosed and the latch snapped closed. Each jaw has a series of alternating indenta-

3. Nance FC: Gastrointestinal anastomosis with a disposable intraluminal stapler, *Contemporary Surg 19:* 11, Dec 1981

4. Ibid, p. 12

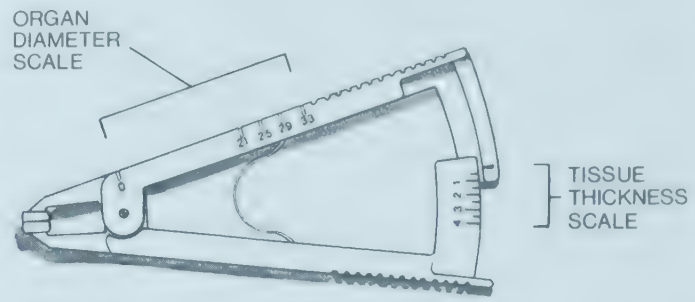
*Trademark

tions, that securely grasp the tissue, and a channel through which a straight Keith needle with a swaged monofilament suture is passed. The result is a ring of uniformly spaced stitches placed around the structure in a purse-string pattern that allows easy pull down of tissue to the center rod while minimizing the tissue cuff. With the device still in place, and using the edge as a guide, the organ is transected with a scalpel. The ideal purse-string is approximately 2 mm from the cut edge of the tissue. This 2 mm margin is attained with the PSD device. If a manual technic is used to place the purse-string suture, the margin should not exceed 5 mm. A cuff greater than 5 mm could prevent the ILS stapler from firing correctly or cause improperly formed staples. The PSD device should not be used on ischemic or necrotic tissue, or on tissue with an indicated diameter larger than 33 mm as measured by the TMD device. Care should be exercised in removal of the PSD device and the lumen should be inspected for missed stitching.

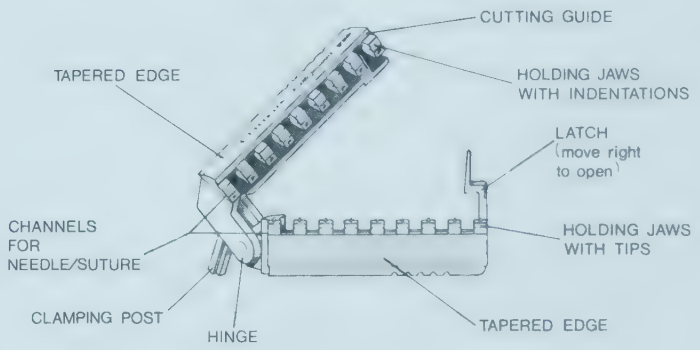
If an enterotomy or gastrotomy is to be used for entry of the ILS stapler into the organ, the incision is placed in a location that will allow the junction of the anvil and head to reach the anastomotic site. Before insertion, the anvil nut must be checked to insure that the anvil is seated level and tightened. The gap must be in the closed position to avoid catching tissue. After insertion through the appropriate gastrotomy, enterotomy or anal entry, the gap between the anvil and head is opened exposing the center rod. The purse-string suture in the proximal segment is tied firmly against the center rod and excess tissue excised. The anvil is inserted into the distal segment, the segments aligned, and the purse-string tied. Redundant tissue and suture must be trimmed prior to closing the gap. With the two tissue segments properly aligned, the instrument is closed to the appropriate predetermined tissue thickness gapsetting on the stapler and to the correct amount of pressure. If there is too little pressure, the anastomosis will leak. If there is too much pressure, the blood supply will be jeopardized and the tissue at the anastomotic site may become necrotic and leak. A black indicator button will protrude from the adjusting knob when the ILS stapler is within its correct operating range *(Fig. 34)*.

The ILS stapler fires a circular staggered double row of stainless steel staples. As they are driven into the tissue and against the anvil, the staples form into a *B* shape *(see Fig. 35)*. The B-shaped

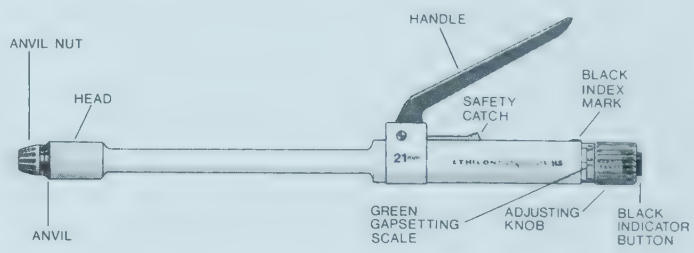
**Fig. 34 ILS disposable intraluminal stapler system**




1. TMD tissue measuring device




2. PSD purse string device




3. ILS intraluminal stapler

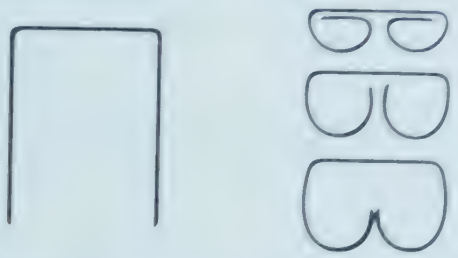
closure of the staples "permit arterioles to carry blood through the stapled portion to the very end of the transected tissue."[5] This helps prevent necrosis. However, "one must be certain that there is not bleeding within the B of the staple of sufficient quantity so that the patient is going to bleed postoperatively.... One must look for this. It is one of the very possible complications of using the stapler."[6] The configuration of the closed staples does allow a degree of elasticity in the closure comparable to that achieved by sutures. Staples act as horizontal mattress sutures to hold the tissue in serosa to serosa approximation. A hand sutured anastomosis directly opposes both serosa and mucosa. "The minute gap between the mucosal surfaces after suturing probably heals by a combination of both primary and secondary intention. On the other

5. Richards V: Staplers in intestinal surgery, *Contemporary Surg 14:* 52-53, June 1979

6. Ibid

hand, healing of the 2 to 4 millimeter gap at the stapled anastomosis is apparently dependent upon secondary intention healing."[7] Tissue is less traumatized by stapling, and procedure is faster.

Fig. 35 Adjustable staple height



A circular knife within the head of the stapler trims the tissue to produce a proper lumen as it cuts through tissue and washer in the anvil. Stapling and trimming both occur when the ILS stapler is fired. A safety catch prevents premature firing.

To fire, the safety catch is drawn back. The handle is squeezed with a firm steady pressure throughout the firing cycle. The surgeon will feel reduced trigger pressure and hear a distinct sound as the instrument completes the firing cycle. To withdraw the ILS stapler from the organ, the surgeon opens the gap, then rotates the instrument 360 degrees to free it from the staple line. One edge of the anastomosis is gently lifted over the rim of the anvil. The integrity of the staple line is inspected after removing the stapler.

The tissue remaining in the stapler also should be inspected. "Staple anastomosis may be considered mechanically sound and hermetic if the rings of tissue around the central rod are intact."[8] Two complete donut-shaped tissue rings with intact purse-string sutures usually indicate complete cutting and a proper stoma. If incomplete, the anastomotic site should be thoroughly checked for leakage and the appropriate repairs made with reinforcing sutures. Then gastrotomy or enterotomy incision is closed.

Components of the PROXIMATE ILS stapler system are discarded after use. They are intended for single patient use and cannot be resterilized.

A training program consisting of surgical films, a reference manual and package inserts is available through ETHICON representatives. It is recommended that first-time users of the ILS stapler review all the components of this training system prior to using the ILS stapler.

7. Polglase AL et al: A comparison of end-to-end staple and suture colorectal anastomosis in the dog, *Surg Gynecol Obstet 152:* 795, June 1981
8. Ibid

*Trademark

### Internal Linear Staples

The PROXIMATE* linear stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues. The linear stapler delivers a double staggered row of stainless steel staples to approximate tissues. Sizes of available staplers vary to accommodate desired staple line length and to accommodate thickness of specific tissue. The 90 mm staplers, for example, are designed for gastric procedures such as gastric partitioning, or for use in the lung. The staple compartment applies either 11 staples in a line of approximately 31 mm, 21 staple line approximately 59 mm, or 33 staple line approximately 92 mm. Use of the stapler is contraindicated on ischemic or necrotic tissue and on pulmonary vessels.

The tissue to be transected or resected is positioned in the stapler jaws of appropriate length. By pushing the remote retaining pin knob, the anvil and staple compartment are aligned to provide the correct staple formation and to prevent compressed tissue from slipping from the jaws. The surgeon adjusts the gap between the jaws by rotating the adjusting knob to the desired reading on the gap setting scale. *(See Fig. 36.)* A "lockout" feature prevents turning the adjusting knob unless the retaining pin is pushed completely forward through the anvil into the distal jaw. The parallel jaws uniformly compress tissue across the entire line.

The gap between the jaws must be adequate for the thickness of the tissues. This may be determined upon the surgeon's experience or in conjunction with the PROXIMATE* TMD tissue measuring device *(see Fig. 34)*. This device can be used throughout the alimentary tract. The TMD is *not* designed for use in procedures involving the lungs. It measures tissue thickness of a collapsed organ segment at a predetermined pressure. If the TMD reading is greater than 3.0 or less than 1.0, the linear stapler is contraindicated.

Staple height is adjustable to compensate for various tissue thicknesses. Settings on the scale correspond to a 1.5 mm and 2.0 mm outside height dimension of closed staple. Tissue blanching and resistance to closing may be observed as final gap setting is achieved. The stapler is ready for firing.

To actuate *(fire)*, the safety is drawn back toward the handle. This will not release unless the gap is set in the firing range. When the trigger is firmly pulled back to the handle, the surgeon will have audible, tactile and visual indications that firing is

complete. The trigger locks into the handle after staples are fired. Prior to removal of the stapler, the edge of the jaw can be used as a cutting guide to transect tissue, or to excise any margin of tissue protruding through the jaws. This will aid in cutting at a proper distance from the staple line. The adjusting knob is rotated to open the jaws. The retaining pin may be pulled back to facilitate removal.

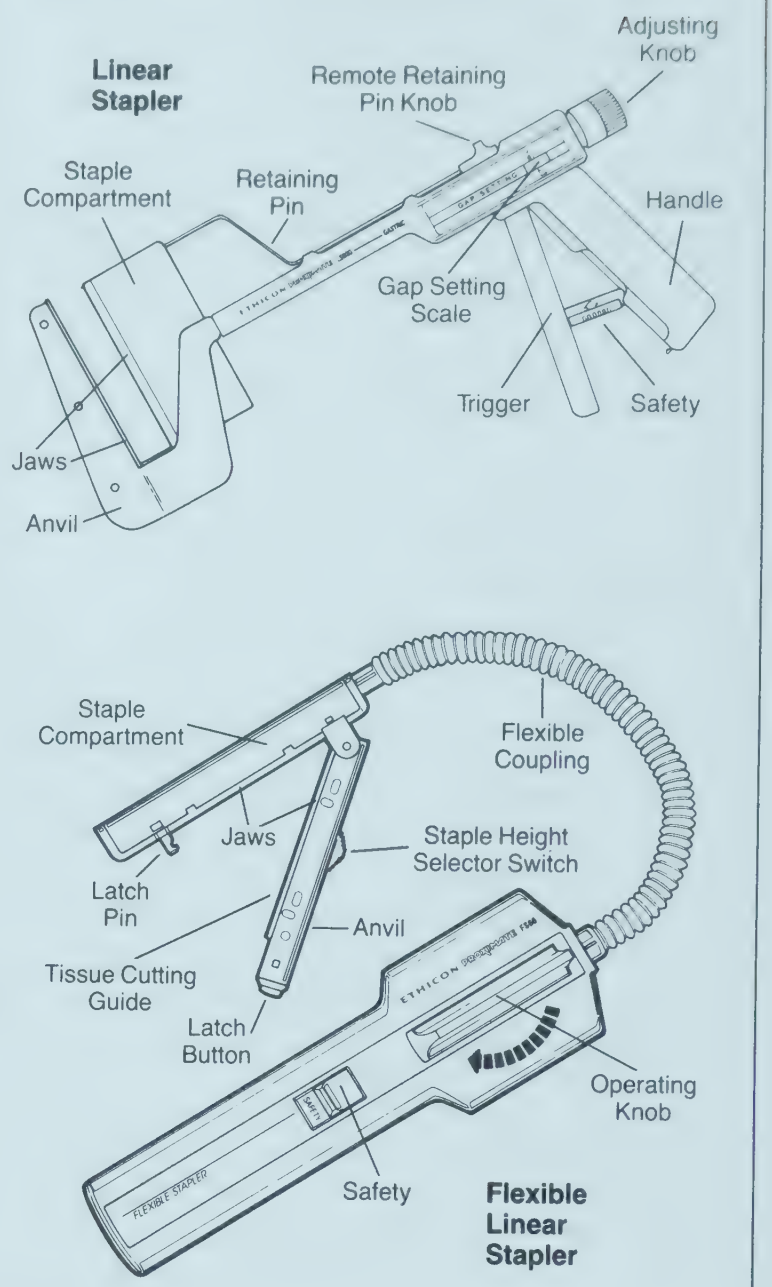
The staple line must be inspected for hemostasis and integrity after removal of the stapler. The linear stapler and tissue measuring device are disposed of after use. They cannot be resterilized.

The PROXIMATE* flexible linear stapler has a flexible coupling between the handle and the jaws that allows versatile placement of the jaws on internal tissues *(see Fig. 36)*. Staplers are available in two types. One type permits selection of an appropriate staple line length for transection or resection in alimentary tract or in thoracic surgery. Either a stapler with 20 staples in a double staggered line of approximately 54 mm or 32 staples in a line approximately 89 mm long may be selected. The other type is designed for gastric applications where thicker tissue is encountered. It applies 32 staples in a line approximatey 89 mm long.

Staple height may, at the surgeon's discretion, be selected to compensate for different tissue thicknesses. The surgeon can select either of two preset closed staple heights, and corresponding gap setting of the jaws, based upon judgment and experience. The proper staple height should be selected prior to closing the instrument on tissue. The anvil of the stapler can be placed either up or down to position the jaws over the tissue to be stapled. An audible and tactile indication will be noted when the jaws are securely latched with the anvil firmly closed over the latch pin. Should resistance to closing be observed due to tissue thickness, the selector switch should be moved to the larger staple height. If the anvil cannot be closed over the latch pin, use of the instrument is contraindicated.

The safety should not be released until the instrument is ready to fire. Then it is slid away from the operating knob. To fire the linear stapler, the operating knob is turned clockwise until it stops. A stop in the handle prevents turning this knob in the

**Fig. 36 PROXIMATE* Linear Staplers**




wrong direction. After firing, the jaws are opened by pushing the latch button to release the latch. The anvil is opened to release the tissue. The staple line must be examined for hemostasis and complete closure. If required, sutures or electrocoagulation may be used for corrective action. The stapler is disposed of after use.

See package inserts inside each box of mechanical wound closure devices for manufacturer's recommended indications for use, contraindications, precautions and operating instructions.

*Trademark

SECTION VII

# The Packaging, Preparing and Handling of Wound Closure Products

## PACKAGING

The packaging of any product aims at protection of the contents and at convenience for the user. At ETHICON, INC., packaging is an integral part of each product. Just as wound closure technology has come of age in the last half of this century, so has the packaging of wound closure products. A number of factors have brought about this development: the diversity of products to meet user needs, the technological advances in packaging materials, the regulatory requirements currently imposed, etc. High standards and criteria are set for all packaging components.

One important principle to prevent infection in an operative wound is that all instruments and supplies used in contact with the wound must be sterile *(free of living microorganisms, including spores)*. Sutures, needles, ligating clips and staples are among the many supplies that must be sterile. The packaging of *sterile* products must meet specific criteria. It must:

1) Protect and preserve product stability and sterility from potential deterioration caused by outside factors such as oxygen, moisture, light, temperature, dust or vermin.
2) Prevent product damage or microbial contamination in transit and storage for long periods of time.
3) Provide identifiable product information.
4) Afford convenient and sterile transfer of the product from the package to the sterile field.
5) Be functional and meet the needs of the users, both surgeons and nursing personnel.

## EASY ACCESS* PACKAGING FOR SUTURES

Most suture materials are prepackaged and presterilized by the manufacturer. These arrive in the hospital, ambulatory surgical center or physician's office ready for use in sealed boxes. They are put in storage areas until needed.

An instant delivery EASY ACCESS packaging system for suture storage, dispensing and delivery was introduced by ETHICON, INC., in 1979. Designed with human as well as clinical factors in mind, this concept complements and enhances efficiency by saving critical time and reducing unnecessary motions. More importantly, the system is designed to provide control over suture storage, suture usage, inventory rotation and cost containment. The system consists of three basic, interrelated elements: the modular suture storage racks, dispenser boxes and primary packets.

### Modular Storage Rack

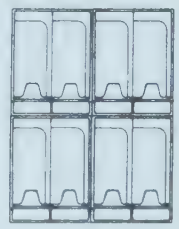
The design of the modular storage racks provides infinite flexibility in suture storage. These racks accommodate both vertical and horizontal dispenser boxes *(see Fig. 37)*. Modules snap together in such a way that they can be expanded either vertically or horizontally, depending on needs and available space. They can be used on shelves, mounted on walls, placed on mobile carts, or assembled in portable units to meet individual requirements of a particular specialty, surgeon or department.

Each module has an inventory control area built into the rack beneath the storage area. This restocking space systematically feeds leftover packets of material back into the proper rotation flow without mixing lots in the boxes.

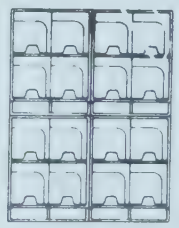
Separation of the various types of suture facilitates selection. Groupings in the modular storage racks may be by material type, by size or by use, i.e., general closure, gastrointestinal, plastic, etc.

**Fig. 37 ETHICON* modular suture storage racks:**

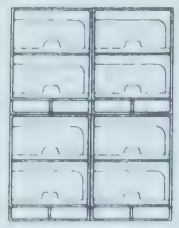
Holds 8 full vertical dispenser boxes, each holding 2 or 3 dozen packets; or, 8 horizontal boxes, each holding 3 dozen packets; or, 16 dispenser boxes, each holding 1 dozen packets or, combinations of box sizes. Can be mounted on wall, or placed on shelf or cart.



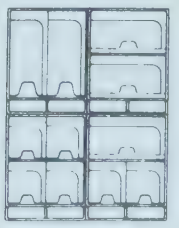
Full-Vertical Dispenser Boxes



Half-Vertical Dispenser Boxes



Horizontal Boxes



Combination of Box Sizes

*Trademark

### Dispenser Boxes

Gravity-fed boxes, both vertical and horizontal *(see Fig. 37)*, dispense suture packets from the opening at the bottom. This opening is large enough to permit removal of eight or less packets at a time. Packets can be counted out as dispensed to help minimize waste.

Graphics, color and symbols on the dispenser boxes are designed to provide positive product identification. The graphics highlight information in order of importance in selecting sutures: the surgical application; the product code number; the size and length, with metric diameter equivalents, and color of the suture strand/s; type of needle/s with size, shape and quantity shown by silhouette/s; absorbable or nonabsorbable material; lot number; and expiration date *(when required)*. Cards with detailed information about the suture material are inserted in some dispenser boxes. Users should be familiar with this information.

All boxes have an arch of color. The eleven colors in the ETHICON* color coding system assist the personnel who store boxes and dispense packets to identify sutures by material. For example, the arch on boxes of plain surgical gut is yellow; on chromic surgical gut it is beige; on silk it is blue, etc. *(Refer to page 25 for complete listing of color codes.)*

Symbols, identified in red, identify CONTROL RELEASE* needle sutures and MULTI-STRAND products *(refer to page 71)*.

A red foam filler is put in each dispenser box on top of the suture packets. When it appears in the window at the side of the box, the foam alerts personnel that it is time to restock the modular storage rack before the dispenser box is completely empty. The few remaining packets can be placed in the restocking space to be used before the new box placed in the rack is opened. This will avoid mixing lot numbers and assure rotation of stock. The dispenser boxes are purposely designed as a *closed* system to deter personnel from putting suture packets from any source into open boxes. Forced box rotation also ensures new, clean boxes to help reduce bioburden and cross contamination.

Most dispenser boxes contain three dozen suture packets. Some boxes dispense two dozen; others have one dozen packets. Both the product code number and statement on the box indicate the quantity initially packed in the box.

By firmly pushing the box into a "lock" in the back of the rack modules, boxes are held securely for easy dispensing of packets.

### Primary Packets

All individual sutures and multiples of suture strands supplied sterile are contained within two or three layers of packaging. The packaging varies depending on the type of product, i.e., needled versus non-needled, size of strand, characteristics of the material, etc. Every packet must have at least two layers to permit sterile transfer from storage in the dispenser box to the sterile field.

1) A peel-apart *overwrap* made of a laminate of foil paper or coated TYVEK† on one side heat sealed to plastic film on the other, encloses every primary packet. The exterior surfaces of this overwrap are not considered sterile.
2) The *sterile inner primary packet* for most products is a hermetically sealed aluminum foil cavity. Microsurgery and some ophthalmic surgery products are contained within a plastic *see-through* packet to enhance visibility of these very fine strands of material.
3) A *paper folder* or plastic organizer encloses or secures all strands with swaged needles. These may be contained within the foil or plastic inner primary packet or it may be overwrapped without other containment.

Each primary packet provides the same functional information and color code as the dispenser box. The tear tab on foil packets also identifies code number, material, size, needle type and *number of needles per packet* to simplify needle counts.

### ETHICON "E" PACK

The "E" Pack is a single peel-apart overwrap containing up to 25 individual primary packets. These packets are secured in plastic organizers to facilitate sterile transfer to the sterile field *(see Method I, Fig. 38)*. Any desired combination of product codes in foil primary packets can be included. Therefore, each pack is customized for a specific procedure, surgeon or surgical specialty.

This packaging concept is designed to save the circulating nurse the time of opening multiple overwraps on single packets. As each box contains five packs, this system can be an effective means for reducing inventory levels of individual product codes. Even though the "E" Pack virtually eliminates suture waste, any unused packets can be returned to ETHICON, INC. for resterilization *(see page 65)*.

*Trademark

†Trademark of E.I. DuPont de Nemours & Co.

## EXPIRATION DATE

Some suture materials have an expiration date stamped on the dispenser box and each primary packet. This is required by the Food and Drug Administration (F.D.A.) to indicate the known shelf life of the material, provided the integrity of the sterile packet is maintained. The stamp clearly indicates the month and year of expiration of the product.

The expiration date is determined on the basis of product stability/sterility testing data available at the time new products developed since 1972 were released. For example, when VICRYL* *(polyglactin 910)* sutures were released in 1974, the expiry dating was approved for two years. In 1975, F.D.A. granted approval for four year expiry dating. This was then extended in 1978 to five years. As longer term stability/sterility study data becomes available, the expiration date for these products may be extended.

"Tests conducted by ETHICON, INC., after storage periods of ten years or longer, show conclusively that the products so tested do not deteriorate with time.... At the same test periods for product stability, sterility stability was also tested. The results proved that our packaging system is capable of retaining the sterility of products so tested in excess of ten years and most likely indefinitely unless the packets are damaged."[1] Expiration dates are not required for older products available more than ten years prior to current F.D.A. regulations. However, all CONTROL RELEASE needle sutures are required to have expiration dates because the needle attachment process, a relatively recent innovation, was a major change in an existing product.

The EASY ACCESS packaging system is designed as a first-in, first-out control system. Boxes are rotated so that oldest sutures are used first and the expiration date on the dispenser box reflects the packets the box contains. This saves the cost and concern of having expired materials in inventory.

## STERILIZATION OF SUTURES

Sutures sterilized by ETHICON, INC. are either irradiated with cobalt 60 or exposed to ethylene oxide gas. Both processes alter proteins, enzymes and particularly DNA of cells to the extent that the microorganisms are unable to reproduce or cause infection. Irradiation and ethylene oxide gas are considered cold sterilization processes because radiation sterilizes at room temperature and ethylene oxide gas at much lower temperatures than dry heat or steam under pressure.

Irradiation sterilization is achieved by exposing products to ionizing radiation, either beta rays produced by high energy electron accelerators or gamma rays from radioisotopes, until they absorb an appropriate sterilizing dose. A pioneer in the use of both beta and gamma irradiation, ETHICON, INC., routinely sterilizes products with irradiation from cobalt 60, which emits gamma rays.

From the standpoint of control, cobalt 60 irradiation is the most reliable of all sterilization processes. "The government regulatory agencies have recognized this fact by allowing, on the basis of appropriate controls of product contamination and radiation dose, the use of dosimetry release in place of the conventional sterility testing . . . *(with biological indicators)*. Cobalt 60 sterilization is the only process which can dispense with routine sterility testing and quarantine because it provides much higher levels of sterility assurance of the products than achievable by other methods."[2]

A few suture materials cannot withstand the effects of irradiation. These materials are gas sterilized. Gas sterilization may employ ethylene oxide in the form of pure gas or mixtures with carbon dioxide or fluorocarbons to eliminate flammability and explosion hazards. The combination of ethylene oxide gas concentration, temperature, humidity and exposure time must be carefully controlled to provide reliable sterilizing cycles. All ETHICON products sterilized by ethylene oxide gas are controlled and released on the basis of biological indicators because of these many variables.

Manufacturers cannot be held responsible for the quality or sterility of suture materials sterilized in the hospital or office. Therefore, this practice is not recommended, except for ETHI-PACK* pre-cut steel sutures and spools or cardreels of nonabsorbable materials supplied nonsterile. All sterile products are labeled *Do Not Resterilize*. The component layers of the packaging materials do not permit exposure to the heat of steam sterilization on the outside of the packet without physical damage to the contents. Foil packets may explode or the seals may become loosened in steam under pressure.

### Resterilization Process

Once removed from their overwraps, the exteriors of primary packets are no longer sterile and must be resterilized before they may again be trans-

1. Artandi C: Industrial sterilization, *Point of View 16* (2): 14-15, April 1979
2. Ibid

*Trademark

ferred to the sterile field. Stripped of overwrap, suture packaged in clean, undamaged, hermetically sealed *foil* packets may be safely rewrapped and resterilized with ethylene oxide gas. However, integrity of packets or product sterility following in-hospital sterilization cannot be guaranteed.

Ethylene oxide gas penetrates through the wrapping material, sterilizes the outside of the foil packet, but does not penetrate through the packet to reach the sterile suture material previously sterilized with irradiation or ethylene oxide. To prevent damage or distortion of the foil packet, the gas must penetrate the wrapping material in heat not exceeding 130°F (54°C) and a vacuum not exceeding 10 inches. Because the sterilization process must be carefully controlled, ETHICON, INC., prefers that unused foil packets be returned for rewrapping and resterilizing.

The term *resterilization* may be a misnomer since it implies the suture is being resterilized when, in fact, the manufacturer only *re-overwraps and sterilizes the outside of sealed primary packets* and does not resterilize the suture material. Sutures of all materials and sizes have been tested for the effects of at least five repeated sterilization cycles and compared with the original test results on the same materials. Repeated sterilization of the primary packet has no deleterious effect on any suture material.

The suture itself remains sterile inside the unopened foil primary packet. Only the outside of the primary packet and the new overwrap are sterilized. All foil packets returned for resterilization are subject to rigid quality control inspection. Any packets which do not meet the inspection standards are rejected. Therefore, if the hospital personnel send packets with blood or other stains, torn notches, delamination, pitting or other damage, these will fail inspection and must be destroyed. This procedure is intended to assure that the sutures returned to the hospital are of the highest quality and safe for use.

## ADVANCED ESTIMATE OF SUTURE NEEDS

During preparations made in advance of the operation, personnel must estimate the suture needs of the surgeon. A file system of preference cards for each surgeon on the staff is maintained in most operating room suites. Among the information on each card is the surgeon's "suture routine," a list of the materials, sizes, needles and/or product code numbers customarily used in specific operations. Personnel who make preparations *(set up)* use the preference card as a guide in selecting sutures. However, prior to dispensing packets, the circulating nurse should have a brief discussion with the surgeon to ascertain whether a change in suture routine is anticipated due to specific patient's needs. Suture requirements should be determined as accurately as possible.

How many suture packets should the circulating nurse open and transfer to the sterile table in advance? Although there is no "right answer" to this question, the circulating nurse must seek the middle of the road between too much and too little. Three major factors should be considered in deciding how many packets to open:

1) The number of strands and needles vary in the packets. Fewer packets will be needed if products with multiple strands of suture material are used.
2) Open *enough* suture to prevent prolonging operative time for the patient and surgeon inconvenience.
3) If *too much* suture is opened, large quantities of leftover packets will remain for resterilization and suture waste may be encouraged.

Expressed another way, when circulating, strip overwraps from only packets that will be needed. When scrubbed, open only what will be used.

When the circulating nurse estimates suture needs accurately, fewer valuable supplies will be wasted. Unexpected suture needs can be obtained rapidly from the storage racks. It is not necessary to overload the table with sutures. When leftover unopened packets are kept to a minimum, little time will be required to clean and prepare them for return to the manufacturer.

## STERILE TRANSFER OF SUTURE PACKETS

The exterior surfaces of the overwrap are not sterile. Inside surfaces of the overwrap and the primary packet within it are sterile as long as the overwrap remains intact and undamaged. In accordance with principles of sterile technic, the circulating nurse may handle the outer surfaces of the overwrap with bare hands. The sterile inner packet must be delivered to the sterile field without contaminating it. This means the circulating nurse must not touch the inner packet or allow it to contact an unsterile surface as it is transferred to the sterile field.

The circulating nurse uses one of two methods to accomplish sterile transfer of primary packets to the sterile field *(see Fig. 38)*. In Method I, the two flaps of the overwrap are grasped with thumbs and forefingers, gripping packet between knuckles.

**Fig. 38 Two methods of sterile transfer of suture packets**

**Method I:** Holding packet flaps between extended thumbs, circulating nurse rolls hands outward to peel packet apart. End of sterile inner packet is exposed and is offered to scrub nurse who grasps it with gloved fingers or sterile instrument.

**Method II:** Circulating nurse stands safe distance from sterile table; rolls flaps of overwrap backward and projects ("flips") foil packet onto table surface.

Using a rolling outward motion, the flaps are peeled apart about a third of the way down the sealed edges. Keeping pressure between knuckles for control, the circulating nurse offers the sterile packet to the scrub nurse. Because all surfaces of the inner packet are sterile, the scrub nurse may remove the packet using either gloved hand or a sterile instrument. In doing so, the scrub nurse must be careful to contact *only* the packet as it is withdrawn from the opened overwrap. This method *must* be used to remove paper folder packets of surgical steel and PROLENE* polypropylene sutures from long straight overwraps, and organizers from "E" packs. Likewise, this method should be used to transfer the flexible lightweight see-through packets of microsurgery and ophthalmic products.

After the operation is underway, the scrub nurse may not be available to receive additional suture packets. When the circulating nurse must deliver the primary packet to the sterile table surface, Method II may be used to flip packets onto the table. "Flipping is a rapid and efficient method of ejecting a rigid item from a package onto the sterile field without reaching over it."[3] To flip a foil packet or rigid paper folder, the circulating nurse grasps the flaps of the overwrap as described for Method I. Using a rolling outward motion, the inner packet is ejected forward as the overwrap is peeled backward. The circulating nurse must stand near enough to the sterile table to project the inner packet onto it, but not close enough to contaminate the table by touching it or extending bare hands over it. Sterile transfer of suture packets by Method II is rapid and efficient when the circulating nurse has acquired skill in its use.

By one of these two methods, suture packets cross the sterile barrier – an invisible point of demarcation between the sterile and the unsterile. Regardless of the setting, i.e., operating room, delivery room, emergency department or physician's office, the person who removes the overwrap from suture packets must remember these points about sterile transfer:

1) Outer surfaces of the overwrap are *not* sterile.
2) Bare hands may contact outside overwrap surfaces *only.*
3) Sterile inner packet containing the suture/s must be transferred to sterile field without contacting a nonsterile object or surface.
4) Bare hands over the sterile field violate aseptic technic.

3. Kohn, ML: Sterile transfer – to flip or not to flip, *Point of View 16* (2): 16, April 1979

*Trademark

## SUTURE PREPARATION IN THE STERILE FIELD

When the sterile inner primary packets of suture have been transferred to the sterile instrument table, the scrub nurse's role in suture use begins. OR personnel who are learning to function in this role appear to be confused more by sutures than by any other aspect of scrubbing. One difficulty they may experience is learning and remembering the sequence in which tissue layers are handled by the surgeon *(review Section IV).* Packets are opened and suture strands prepared according to the surgeon's preference card. However, the experienced scrub nurse prepares sutures in the same sequence as the surgeon will use them. Most often ligatures or ties will be used in subcutaneous tissue shortly after the incision is made, unless the surgeon prefers to use the electrosurgical unit to coagulate severed blood vessels. Hence, these are prepared first. After the ligating material has been prepared, the scrub nurse may open a few other packets and prepare the strands for suturing *(sewing or stitching).* This frees the scrub nurse to hand instruments and supplies as needed by the surgeon at the beginning of the operation.

The experienced scrub nurse seldom finds it necessary to prepare large amounts of suture material in advance. By watching the progress of the operation closely, listening to comments between surgeon and assistants, and evaluating the situation, suture needs can be anticipated. The scrub nurse can utilize free moments to prepare just enough suture to stay one step ahead of the surgeon. The experienced scrub nurse seldom has more than a few strands remaining at the end of the operation.

Scrub nurses with limited experience have a tendency to open and prepare too many sutures. This appears to contribute to their sense of security and make them feel able to cope with any eventuality. But consider that when the surgeon opens the peritoneum lining the abdominal cavity, for example, a disease or condition may be found which alters plans for the operation and anticipated use of sutures. Opened packets would be wasted.

Once the scrub nurse or technician feels competent and understands the operation being performed, most often he or she will find enough time is available to open and prepare sutures as the operation progresses. The experienced scrub nurse seeks the "middle road" by preparing just enough sutures to start the anticipated procedure. All the

sutures required do not need to be opened until certain it will be done. The sutures needed will depend on the nature of the operation and the surgeon's technic.

Closure of the wound following abdominal surgery may sound complicated to the person new to the scrub role. Keeping the letters *PFS* in mind may be helpful to the newcomer. *P*eritoneum, *F*ascia, and *S*kin are the three tissue layers almost invariably sutured following abdominal operations, and the layers are closed in this order. A few stitches may be placed in muscle tissue and subcutaneous tissue in addition to peritoneum, fascia and skin. Astute observation and experience gained by the scrub nurse during active participation in operative procedures eventually will completely dispel confusion about sutures and suture use.

Nearing the end of the operation, the scrub nurse may have material remaining from ligating subcutaneous blood vessels. The surgeon's suture routine often specifies the same material and size for a few sutures in the subcutaneous layer of wound closure. When this is the case, the scrub nurse should use remaining ligating material for this purpose rather than opening an additional packet.

On occasion, the surgeon needs "only one more suture." The scrub nurse may have lengths of the material remaining that are shorter than those prepared originally. The scrub nurse should not be reluctant to ask the surgeon whether the strands will serve the purpose before opening a new packet. Most surgeons are cooperative in efforts to conserve valuable supplies.

## Preparation of Ligating Material

Surgeons use ligating material *(ties)* in one of two ways: (1) as single strand ties *(free or freehand)*, or as (2) continuous ties unwound from a reel or other device. Occasionally the surgeon wishes to use a stitch to close the severed end of a large blood vessel for security against knot slippage. This stitch is called a transfixion suture or suture ligature. In some operating rooms, it is referred to as a "stick tie," while in other suites a "stick tie" is a long strand clamped on a hemostat.

Length of freehand *(single strand)* ties is determined by depth of the wound. In subcutaneous tissue, quarter lengths (*about 14 inches*) usually are long enough for ligating. As the surgeon works deeper in the wound, he may require freehand ties from 18 to 30 inches long. Packets of pre-cut lengths of 18, 24 or 30 inch strands are available for freehand ties. Steps in preparation of standard length strands for freehand ties and suture ligatures are shown in *Fig. 39*.

Many surgeons prefer continuous ties. Some prefer LIGAPAK* ligature. The material is supplied on a disc-like plastic dispensing reel which is held in the palm of the hand as blood vessels are ligated. These radiopaque reels are color coded by material. The size of the suture material is indicated on the reel. The few steps in preparation of this reel for ligating are illustrated in *Fig. 40*.

Other surgeons who like continuous ties find that ligating material rewound on a rubber reel, a gauze sponge, metal bobbin or other device meets their needs. The scrub nurse must prepare these for the surgeon.

The number of packets of ligating material required to tie off subcutaneous vessels *(bleeders)* varies with patient size and age, amount of bleeding, type of operation, length of incision and surgeon technic. An abdominal incision 8 to 12 inches long might require an average of one to three packets to ligate the subcutaneous blood vessels.

## Preparation of Suture Material

Dispenser boxes and primary packets are color coded by suture material to facilitate identification by both the circulating and scrub nurses. The scrub nurse opens the sterile primary packet and prepares the suture strand for the surgeon. A suture packet may contain:

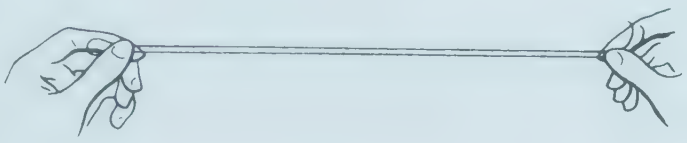
1) One standard length strand of non-needled material, 54 inches *(135 cm)* of an absorbable or 60 inches *(150 cm)* of a nonabsorbable, which may be cut into half, third or quarter lengths for ligating or threading as shown in *Fig. 39*.
2) Pre-cut lengths of non-needled material for ligating or threading. These may be in LABYRINTH packet or straight tube designed for delivery of one kink-free strand at a time. SUTUPAK* pre-cut sterile sutures are removed from the packet and placed in a fan-folded towel *(suture book)* as shown in *Fig. 41*.
3) Single strand of material with a single or double-armed swaged needle/s. Microsurgery and some ophthalmic needles are secured in a "needle park" inside a see-through packet. All other needles are protected within an inner folder or other specific channel within a paper folder.

   All single strand needled sutures sealed in foil are in EASY ACCESS* packets designed with two options as shown in *Fig. 42*.

*Trademark

**Fig. 39 Preparation of standard length strands**

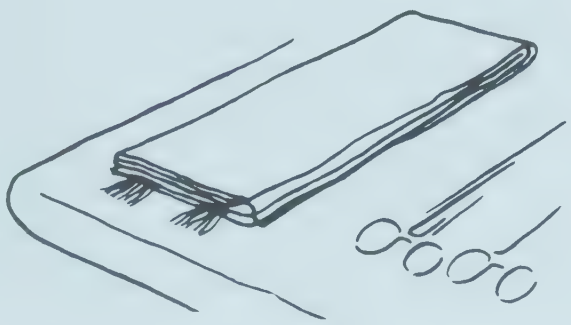
1. To prepare cut lengths of surgical gut, place standard length coil around fingers of left hand. Grasp two free ends with right hand and unwind to half length.



2. Maintain loop in left hand and two free ends in right hand. Gently pull surgical gut strand to straighten.

3. To make ⅓ lengths: Pass one free end of strand from right to left hand. Simultaneously, catch a loop around third finger of right hand. Make the strands equal in thirds and cut at loops with scissors.

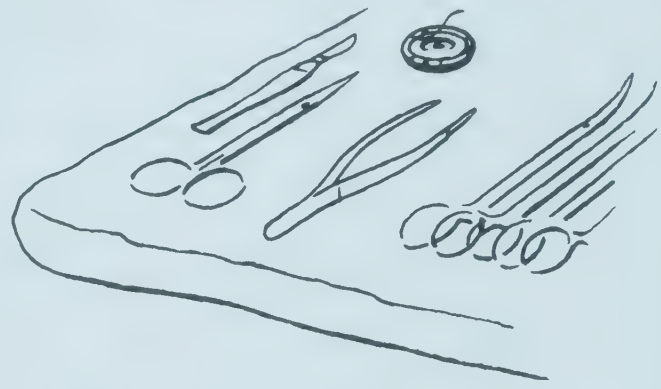
4. To make ¼ lengths: Pass both free ends from right to left hand, simultaneously catching a double loop around the third finger of right hand. Cut the loops.



5. Place packets or strands in "suture book" with ends extended far enough for rapid extraction.

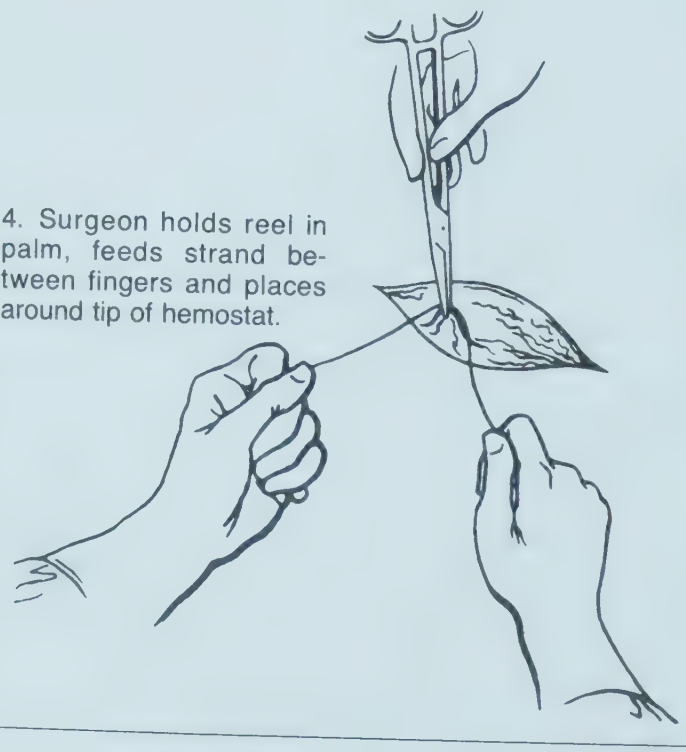
**Fig. 40 Continuous ties on plastic disc-type reel**

1. Tear open foil packet containing appropriate material on reel.



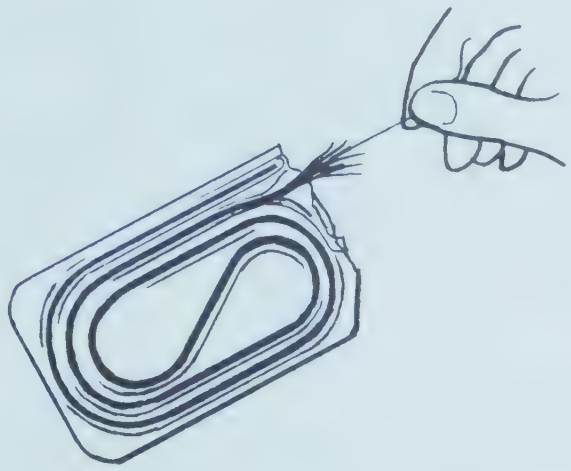
2. Extend end of strand slightly for easy grasping. Place reel conveniently on Mayo tray.

3. Hand to surgeon as needed, being certain end of ligating material is free for his grasp.

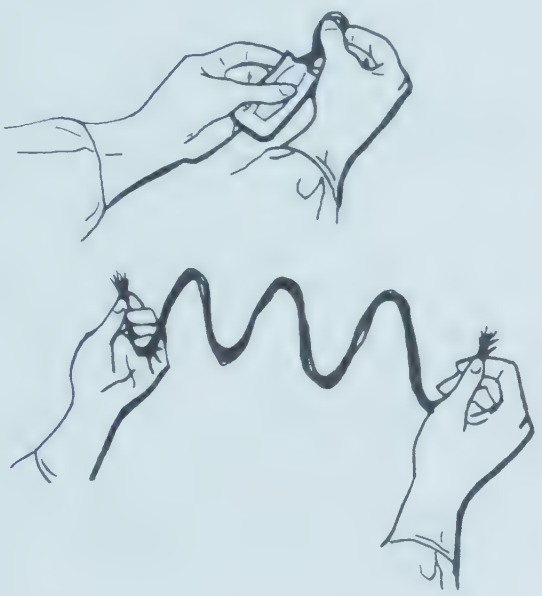


4. Surgeon holds reel in palm, feeds strand between fingers and places around tip of hemostat.

**Fig. 41 Pre-cut sutures: ties or suture ligatures**

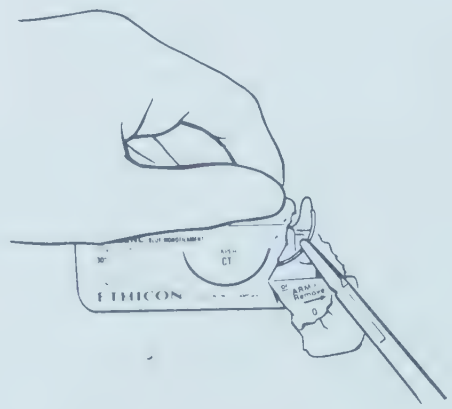


1. Nonabsorbable pre-cut length is removed one strand at a time from the LABYRINTH packet when the surgeon is ready to use it.

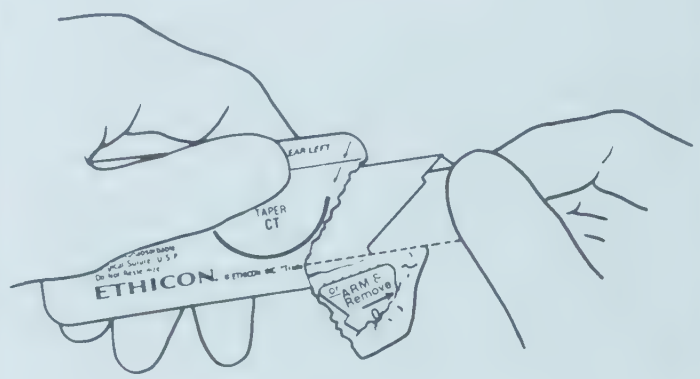


2. Extract pre-cut strands of SUTUPAK* sterile sutures, either absorbable or nonabsorbable. Straighten surgical gut with gentle pull. Place strands in "suture book" as shown in Fig. 39.

**Fig. 42 EASY ACCESS* packets: two options for single strand needled sutures**




1. Arm needle directly from packet and deliver single suture to surgeon.




2. Pull tab and tear along perforation and remove inner folder.

a. The needle can be armed in the needleholder and the single strand delivered directly to the surgeon from the packet.
b. The inner paper folder can be removed to prepare several sutures for delivery as needed.

4) Multiple suture strands, each swaged to a single needle or double-armed. These are appropriate for those procedures requiring numerous interrupted sutures of the same type. Use of these products saves the scrub nurse the time necessary to open many single strand packets. As fast as the surgeon uses one suture, the next one is armed without delay of opening packets or threading needles.

MULTI-STRAND packets are labeled with the symbol (MS/ ) that denotes multiple strands/number of strands of ATRALOC* surgical needles per packet. MULTI-STRAND packets may contain three to ten swaged sutures. The inner folder for these products is white.

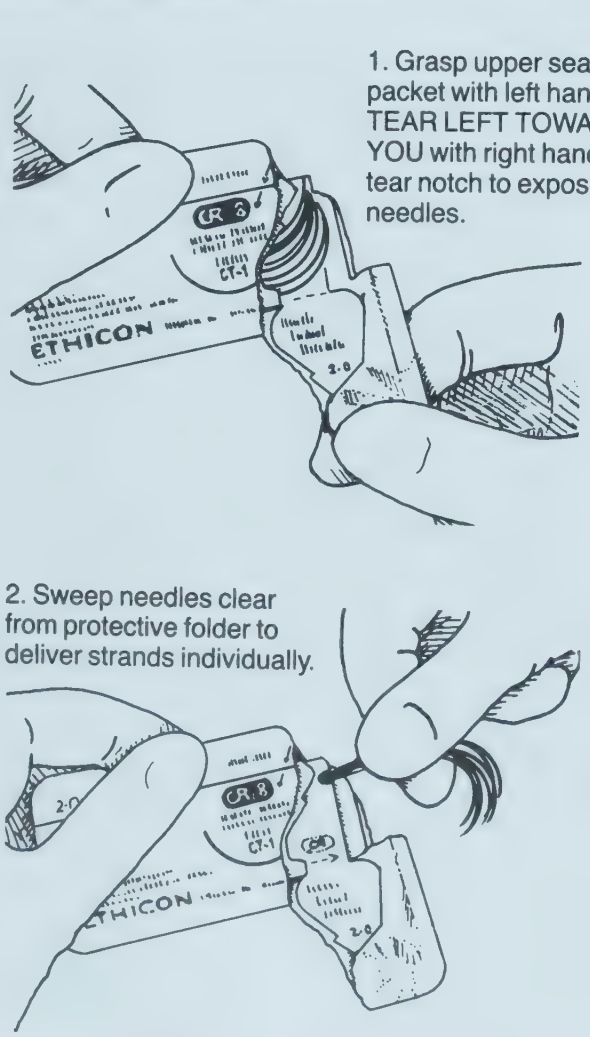
All packets of CONTROL RELEASE needle sutures have multiple strands of 8 or 5, designated (CR/8) or (CR/5) . These sutures are in foil packets designed for single strand delivery, i.e., delivery of one strand at a time

*Trademark

directly from the organizer or paper folder. CONTROL RELEASE needle sutures are in one of two types of packets, depending on the suture material:

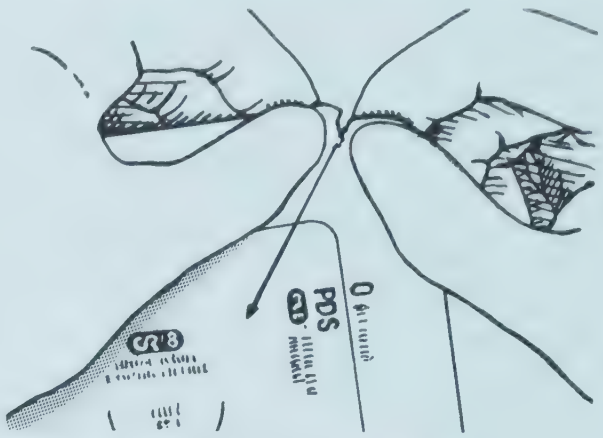
a. Single strand delivery *folder*, as shown in *Fig. 43*, for Coated VICRYL* *(polyglactin 910)* suture and the braided or twisted nonabsorbable sutures. These materials straighten as they are delivered from the folder. The scrub nurse has the option of delivering each suture individually from the opened foil packet, or removing the folder and placing it in suture book. The inner folder for these products is red with the symbol in black.
b. Single strand delivery *organizer*, as shown in *Fig. 44*, for PDS* *(polydioxanone)* suture and surgical gut. This organizer presents these monofilament sutures in manageable coils. Needles can be armed directly from the organizer.

**Fig. 43 Single strand delivery folder: CONTROL RELEASE needles on Coated VICRYL sutures and nonabsorbable sutures**

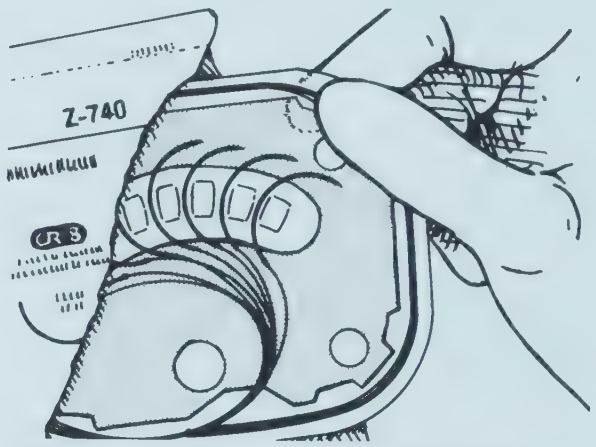



*Trademark

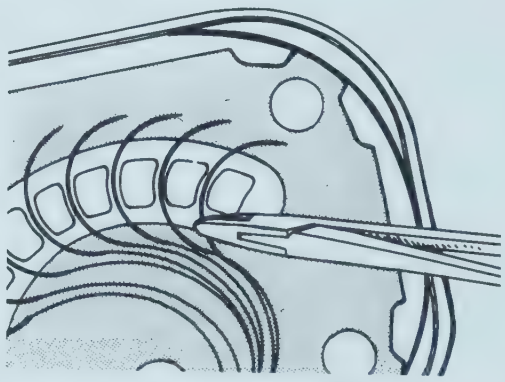
**Fig. 44 Single strand delivery organizer: CONTROL RELEASE needles on PDS sutures and surgical gut**



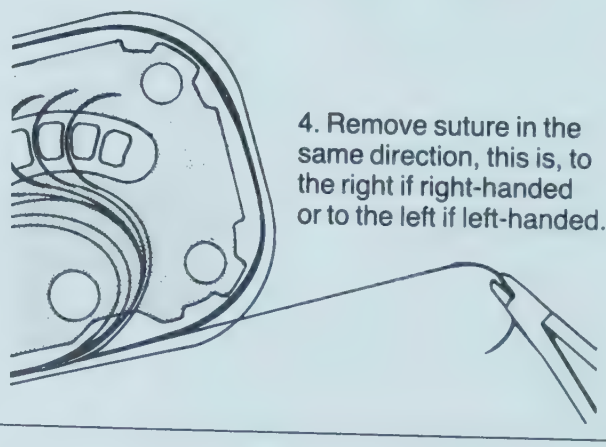

1. Grasp upper seal of packet with left hand. Place right hand to right of tear notch and TEAR LEFT TOWARD YOU.




2. Remove suture organizer from foil packet.



3. To arm, the needles should be pointing in same direction as the hand holding the needleholder.



4. Remove suture in the same direction, this is, to the right if right-handed or to the left if left-handed.

Suture material is packaged dry with the exception of surgical gut and collagen. A small amount of fluid, chiefly alcohol and water, is injected into packets of these natural absorbable materials to maintain pliability. The scrub nurse should open these packets over a basin to prevent any solution from spilling on the sterile field.

*All* needles should be counted after packets of swaged sutures are opened, according to established hospital procedure. The packets can be retained to facilitate verification of the final count.

## Importance of Good Handling Technic

It is essential that the scrub nurse learn to handle each suture material correctly in order to preserve its tensile strength. The patient's wound has little or no strength of its own during the first postoperative week. Sutures or mechanical devices bear the burden of holding the tissues together during this period. *Only* if the quality and integrity of the wound closure materials are preserved during the handling and preparation, can they be expected to provide the strength essential to uneventful wound healing.

With all suture materials, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie. Caution must be exercised in handling suture material. "Application of clamps or forceps or rough handling can damage or weaken even synthetic suture and lead to early failure."[4] Other correct handling information for preservation of tensile strength of both absorbable and nonabsorbable suture materials is provided in *Figs. 45 and 46.*

**Fig. 45 Preservation of tensile strength: Absorbable sutures**

**Protect absorbable sutures from heat and moisture**

1) Store suture packets at normal room temperatures. Avoid prolonged storage in hot areas, for example, near steam pipes and sterilizers.
2) Refrain from soaking absorbable sutures. Excessive exposure to water or saline will reduce the tensile strength. Prolonged containment in a moist suture book has the same effect.
3) Surgical gut can be moistened if strands dry out before use. Dip *momentarily* in *tepid* (room temperature) water or saline to restore pliability. Rinsing is necessary *only* for surgical gut or collagen suture to be used in the eye.
4) Synthetic absorbable sutures must be kept dry. Use strands directly from packet, as frequently as feasible. Store strands in *dry* suture book, if necessary.
5) Absorbable sutures cannot be steam sterilized.

**Preserve tensile strength of absorbable sutures during preparation**

1) Limit contact between rubber gloves and suture strands to absolute minimum necessary for preparation. Excessive handling of surgical gut with rubber gloves can cause fraying.
2) Straighten strands with gentle steady, even pull. Jerking and tugging can weaken sutures.
3) Refrain from "testing" strength of strands.

**Fig. 46 Preservation of tensile strength: Nonabsorbable sutures**

**Silk and Dermal**
*Dry* strands are stronger than wet strands. Silk wet with water loses up to 20% in strength. Store strands in dry towel.

**Cotton and Linen**
*Wet* strands are stronger than dry strands. Moisten strands prior to use. Cotton wet with water gains up to 10% in strength.

**Surgical Stainless Steel**
Handle carefully to avoid kinks and bends. Any wire suture when bent repeatedly over sharp angles can work harden the wire and cause breakage.

*Do not* steam sterilize on spool or in contact with wood. Lignin is leached from wood subjected to high temperature and may cling to suture material.

Stainless steel is the only suture material that can be steam sterilized without loss of tensile strength to some degree.

**Polyester Fiber**
Can be used wet or dry because it is unaffected by moisture.

**Nylon**
To straighten kinks or bends, "caress" nylon strand between gloved fingers a few times.

**Polypropylene**
Can be used wet or dry because it is unaffected by moisture.

Straighten strands with a steady pull.

4. Nichols WK et al: Anastomotic aneurysms following lower extremity revascularization, *Surgery 88* (3): 369, Sept 1980

## SUTURE HANDLING TECHNICS

The following summarizes some points to remember and observe in handling suture materials and surgical needles.

### Circulating Nurse

1) Consult the surgeon's preference card for suture routine.
2) Read the label on the dispenser box. Check for size and type of both suture material and needle/s. Note number of strands per packet. Fewer packets will be needed if MULTI-STRAND or CONTROL RELEASE sutures are used.
3) Dispense from the box for transfer to the sterile field only the type and number of packets required for the procedure. It is costly to the hospital to open an excessive amount.
4) Use sterile technic in opening the overwrap. Transfer the inner packet to the sterile field by offering it to the scrub nurse or by projecting *(flipping)* it onto the table from a safe distance to avoid contamination *(see Fig. 38)*.
5) To open long straight packets, peel overwrap down six to eight inches and present to the scrub nurse. Do not attempt to strip and flip the inner folder.
6) Keep an adequate supply of the most frequently used sutures readily accessible.
7) Rotate stock. Use older suture stock first. Fi-Fo–First In, First Out–is an important rule to follow in keeping suture inventories current and to avoid expiration of dated products.
8) Count needles with the scrub nurse per hospital procedure.

### Scrub Nurse

1) Read the label on the primary packet before opening. When a variety of sutures are available, reading the label helps avoid the waste of opening the wrong packet. Also note any directions for opening, for example, TEAR LEFT ↙ on EASY ACCESS packets.
2) Carefully tear open foil packets at notch. With label facing up *(visible)*, grasp packet with left thumb along topseal *(see Fig. 42)*. Grasping the packet with pressure on the foil cavity may damage the suture or needle. With right hand, grasp right-hand corner at tear notch. Tear straight down or slightly left as indicated on the packet, to expose inner folder or suture. *Do not use scissors* to open foil packets.
3) Leave pre-cut lengths in LABYRINTH packet or in tube of ETHI-PACK pre-cut sutures and place on Mayo tray. Strands can be removed one at a time.
4) Hold single strand taut for surgeon to grasp for use as freehand tie *(see Fig. 47)*.
5) Remove inner folder from foil packet and open as directed. Or, remove exposed suture with sterile hand; no instrument necessary. Or, arm needle directly from packet and *slowly* remove for delivery of a single strand to the surgeon *(see Figs. 42, 43 and 44)*.
6) Count needles with the circulating nurse, per hospital procedure.
7) To simplify needle counts, the tear tab on foil packets identifies code number, material, size, needle type and number of needles per packet. This tab or the entire packet can be retained for product identification during the procedure and/or until needle counts are completed.
8) Nonabsorbable and synthetic absorbable sutures are packaged dry. These materials need not be rinsed. Cotton should be used wet. Dip it in sterile distilled water or other irrigating solution. If the surgeon prefers to use sutures wet, dip momentarily. Do not soak. Silk should be used dry. Excessive exposure to water will reduce the tensile strength of the absorbables.
9) Avoid pulling or stretching surgical gut or collagen. Excessive contact with rubber gloves can also weaken and fray fine gut or collagen. Because these materials lose tensile strength due to absorption of water, they should not be soaked. Dip momentarily in tepid *(room temperature)* water or saline to restore pliability if strands become dry.
10) Ophthalmic tissues are extremely delicate. To avoid introducing a possible irritant, always rinse surgical gut and collagen suture before use in the eye. Packets of these materials contain fluid to maintain pliability of the strand. Although chiefly alcohol and water, this may be irritating to ophthalmic tissues.
11) Pulling on needles to straighten sutures can cause premature separation of CONTROL RELEASE needle suture.
12) Always protect the needle to prevent dulling points and cutting edges. Clamp needleholder forward of the swaged area, about ¼ to ½ the distance from the swage to the

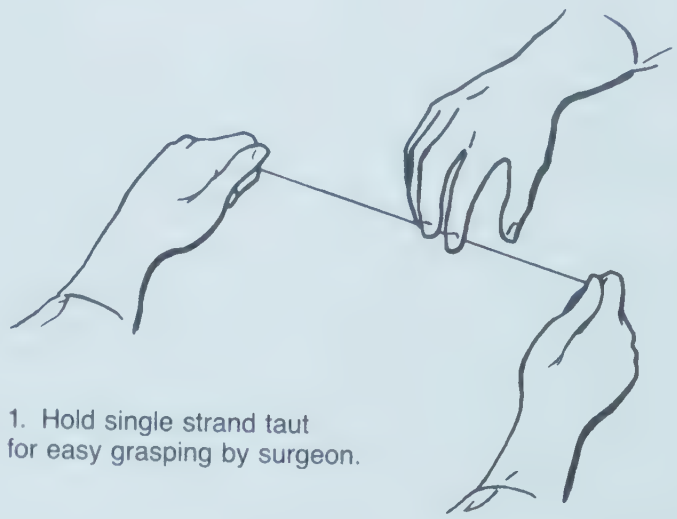
point. Refer to *pages 48–50* for other tips on care and handling of needles.

13) Microsurgery sutures and needles are so fine and delicate that the scrub nurse may have difficulty seeing and handling them. These products are packaged with the needles parked in foam to protect delicate points and edges. The needles may be armed directly from the foam "needle park." If the microsurgeon prefers to arm the needle, the removable, orange-colored tab may be used to transport the needle into the microscopic field.
14) Handle all sutures and needles as little as possible. Sutures should be handled without using instruments unless absolutely necessary. Clamping instruments on strands can crush, cut and weaken them.
15) Cut sutures only with suture scissors; surgical steel with wire scissors.
16) When requesting additional suture from the circulating nurse, estimate needs as accurately as possible.
17) When unopened suture packets remain after the operation, place the cleaned and undamaged packets in the collection box to be returned to the appropriate manufacturer. Leftover strands from opened packets must be discarded.

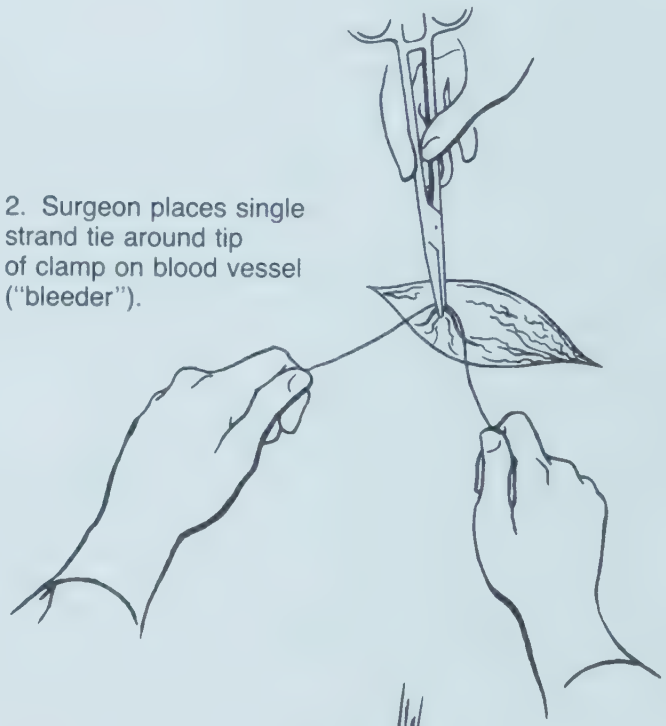
**Surgeon**

1) Care should be taken to avoid damage to the strand when handling. This is particularly critical during use of fine sizes of monofilament material. Touch strand only with gloved hand or *closed* blunt instrument. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.
2) A rubber shod hemostat may be clamped on suture to anchor free needle on a double-armed strand until the second needle is used.
3) To distribute tension along a continuous suture line, use a *closed* needleholder or nerve hook. Avoid crushing the strand.
4) When tying knots, use appropriate technic for the specific suture material *(refer to page 23)*. With synthetic sutures, knot security requires the standard surgical technic of flat and square ties with additional throws if indicated by surgical circumstances and the experience of the surgeon.

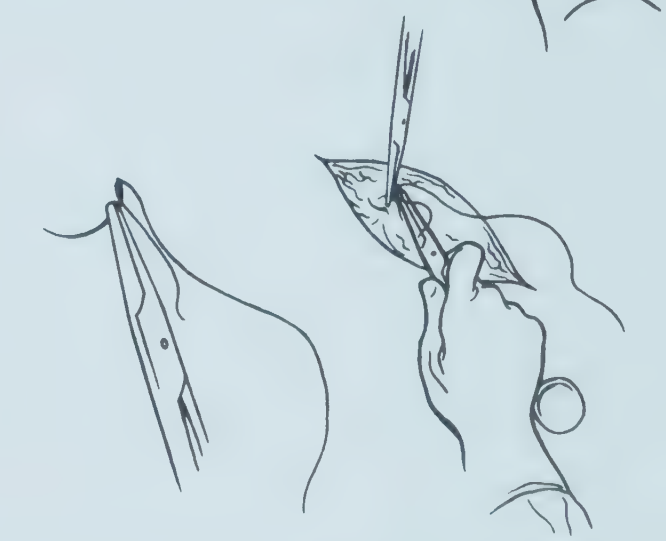
**Fig. 47 Single strand ties; suture ligatures**



1. Hold single strand taut for easy grasping by surgeon.



2. Surgeon places single strand tie around tip of clamp on blood vessel ("bleeder").



3. If blood vessel is large, surgeon may wish to transfix it or suture it closed. Single strand tie is threaded on an eyed needle and used as a suture ligature or transfixion suture.

## UNOPENED PRIMARY PACKETS FOR RESTERILIZATION

Some suture manufacturers offer a Resterilization Service (R/S) to hospitals. Unopened, undamaged foil packets remaining after each operation are collected and returned to the manufacturer to be rewrapped and resterilized. Proper care of leftover packets is an essential part of this service.

### Scrub Nurse Responsibilities

1) Estimate suture needs as accurately as possible to keep leftover packets to a minimum.
2) Keep packets clean during operation. Cover unopened packets with sterile towel and remove packet with forceps used only for this purpose.
3) Inspect leftover packets for cleanliness at end of operation. If blood or fat is present on packets, remove with damp sponge and dry packets thoroughly.
4) Place clean, dry suture packets in plastic bag inside collection box. Place other leftover articles *(knife blades, skin clips and the like)* in their proper place–*not in the suture collection box.*
5) In some operating rooms all operations are considered contaminated. Per established routine, unopened suture packets may be handled in one of two ways:
   a. Discard packets in the trash.
   b. Decontaminate packets by soaking for three hours in aqueous CIDEX† activated dialdehyde solution. Remove from solution, rinse and dry. Place packets in regular collection box. *(To avoid damage, foil packets should not be soaked in detergents, disinfectants or any other chemical solution except* CIDEX *solution.)*

### O.R. Supervisor Responsibilities

1) Personally check, or delegate responsibility for checking, contents of suture collection box before it leaves the OR.
2) Allow only clean, dry, unopened and undamaged packets to be returned in the box. See that surgical instruments, laparotomy pads and other items have not been placed in the suture box.
3) Check to see that suture packets are being returned to the correct manufacturer when more than one brand is used in OR.

†Trademark of SURGIKOS, INC.



4) Do not wrap groups of sutures with rubber bands or by other means. This can cause damage to the seals, plus cause a delay in processing, since these must be removed by hand.
5) Tie the plastic bag securely.
6) Label the box clearly with manufacturer's address and hospital return address, including department.
7) Close resterilization carton securely and return to manufacturer by mail.

### Manufacturer Responsibilities

1) Decontamination of contents of box before personnel handle packets.
2) Inspection of packets.
3) Enclose packets in new overwraps and seal.
4) Resterilization. Suture inside undamaged packet remains sterile. Only exterior packet surfaces and overwrap are sterilized in the resterilization process used by ETHICON, INC.
5) Sterility testing.
6) Return reprocessed, sterile suture packets to hospital as promptly as possible. Approximately ten weeks are required for transit time, reprocessing and sterility culture tests.

## PACKAGING OF MECHANICAL DEVICES

The packaging system for sterile disposable staplers and other mechanical wound closure devices produced by ETHICON, INC., has two basic components: the dispenser boxes and the blister packs.

### Dispenser Boxes

The sizes and shapes of the dispenser boxes vary by type of product. With the exception of internal staplers, all products are in horizontal boxes with a large dispenser opening near the bottom for dispensing blister packs individually.

The dispenser boxes of ligating clips have the same graphic design as the horizontal suture dispenser boxes. They fit into the modular storage rack.

All stapling products have a silhouette of the instrument/device as a part of the graphics on the box to supplement the written product identification.

The number of instruments or devices per box varies by product.

Detailed product information sheets or folders are inserted in every box. The user of these products should be familiar with this information prior to using mechanical wound closure products.

**Blister Packs**

All sterile mechanical products are contained within a pre-formed clear plastic blister, hermetically sealed with a peelable TYVEK® lid. The lid also serves as the product label.

The circulating nurse should not remove blister pack from dispenser box until the surgeon determines the size instrument or device to be used, e.g., size stapler or ligating clip.

To open stapling instruments, the circulating nurse peels the lid back by holding the blister pack firmly in one hand and pulling the lid toward self. The instrument or device is presented to the scrub nurse, who lifts it from the blister pack. Do *not* flip or drop stapling instruments onto the sterile field. This could dislodge the staples and make the instrument inoperable.

Ligating clip cartridges and other devices can be flipped onto the sterile field, with method as described for suture packets *(see Fig. 38, page 67)*.

All products are guaranteed sterile, unless package has been opened or damaged. These products are intended for single patient use and are disposed of after use. If the package is opened and the product not used, it should be discarded. Do not resterilize disposable mechanical products.

SECTION VIII

# Miscellaneous Surgical Products

## BONE WAX

ETHICON* bone wax is a sterile mixture of beeswax and isopropyl palmitate, a wax-softening agent. It is opaque and has a waxy odor. Bone wax achieves local hemostasis of bone by acting as a mechanical *(tamponade)* barrier. It does not act biochemically and is minimally resorbable.

Bone wax may be used for the control of bleeding from bone surfaces. It should be used sparingly. Excess bone wax should be removed from the operative site. It may inhibit osteogenesis and may act as a physical barrier to the reparative process. Bone wax should not be used where rapid osseous regeneration and fusion are desired. Mild inflammatory reactions have been reported in tissues immediately adjacent to the site of implantation. Studies have suggested that bone wax, as a foreign body, may impair the ability of the cancellous bone to clear bacteria.[1] In animal models, the local accumulation of foreign body giant cells has been observed. Histologic examination has revealed the appearance of macrophages and occasionally polymorphonuclear leukocytes and lymphocytes.

Bone wax is available sterile in individual foil envelopes, each containing 2.5 grams, and packaged in an individually sealed overwrap packet. The packet should be opened just prior to use to minimize the possibility of contamination and excessive drying. Bone wax should be used immediately after removal from the packet. Using sterile technic, it should be warmed to the desired consistency by manipulation with the fingers or by immersion of unopened foil packet in a warm sterile solution.

Bone wax should not be resterilized or subjected to excessive heat.

## CARGILE* MEMBRANE

This membrane is a thin sheet of tissue made from the submucosal layer of the cecum of the ox. Although still available in a 4 x 6 inch sheet *(10 x 15 cm)*, its use is infrequent. It may be used to cover surfaces from which peritoneum has been removed to prevent adhesions, for isolating ligations, and as a covering for packing material in submucous nasal resections. It also is used as a dural substitute in neurosurgery.

## FASCIA LATA STRIPS

Heterogenous strips of fascia lata are obtained from the fibrous connective tissue that covers the thigh muscles of beef cattle. An autograft of fascia lata may be stripped from the patient's own thigh.

Fascia lata contains collagen, however, it is not a truly absorbable material. It remains a living tissue and becomes part of the tissue it supports. It increases the amount of tissue present to strengthen weakened fascial layers or to fill in defects in fascia. For example, it may be used to strengthen abdominal fascia in the repair of hernia or as a support for the bladder in incontinent patients. Since the advent of synthetic and metallic meshes, heterogenous strips, ¼ by 8 inch *(.64 x 20 cm)*, of fascia lata are used infrequently.

## CORNEAL BEADED RETRACTION SUTURE

When ophthalmologists extract a cataract, it may be desirable to lift the cornea to gain access to the anterior or posterior chamber. This can be accomplished by using a tissue forceps, which potentially could cause corneal trauma. Another option for the anterior segment surgeon is to use a corneal beaded retraction suture, which is potentially less traumatic. A small bead of epoxy is attached to the suture strand, either silk or Coated VICRYL* *(polyglactin 910)* suture swaged to a MICRO-POINT* spatula needle. The suture is placed through the cornea and pulled through to the bead until it is flush with the cornea. The surgeon then can lift up on the suture to elevate the cornea for easy placement of an intraocular lens.

## LACRIMAL STENT

A lacrimal stent is used to prevent an injured tear duct from closing. This can happen as a result of a traumatic injury or surgical intervention. This stent remains in place until healing is completed, two to four weeks in most patients.

The ETHICON* lacrimal stent consists of either one *(single-armed)* or two *(double-armed)* stainless steel probes swaged to a length of medical grade silicone tubing. The stent is indicated for use in the reconstruction of the lacrimal outflow system. Specifically, it is useful in lacerated canaliculus repair, clearance of lacrimal obstruction, dacryocys-

1. Johnson P, Fromm D: Effects of bone wax on bacterial clearance, *Surgery 89* (2): 206-209, 1981

*Trademark

torhinostomies and fistulizing of the outflow system to the tear lake in cancer resection, and other outflow system reconstruction. The availability of multiple sizes permits the surgeon to choose the lacrimal stent most appropriate for each operative procedure.

The single-armed *(one probe)* stent is used for stenting of only one canaliculus. It has a button stopper, also composed of medical grade silicone, at the end of the tubing to position and secure the stent in place. All stents are supplied sterile.

## LOOPED SUTURE

The looped suture product is a 48 inch *(20 cm)* strand of ETHILON* nylon suture, size 0 black monofilament, with both ends swaged to a single taper point needle. It is used for continuous closure of the fascia in the abdominal wall. The suture is initially placed by passing the needle through the fascia from within out, at one end of the incision. The needle is passed through the opposite wound edge, from without in, and the needle passed through the loop. The locking stitch lies beneath the wound edge. The double strand is run over and over to the other end of the incision. The last stitch is completed by bringing the needle from without in, cutting one strand, and passing the needle through the opposite wound edge from without in. The needle is cut off and the suture ends tied. The knot remains inverted under the fascia. The technic is simple and reliable.

## RETENTION SUTURE DEVICES

When retention sutures are used *(refer to pages 12 and 32)*, some type of device is employed to prevent cutting the skin and to displace or eliminate pressure. Frequently some of these devices only compound the problems. Use caution to avoid placing excessive tension on retention sutures.

### Retention Suture Bolsters

Retention suture bolsters are sterile 2½ inch *(6 cm)* lengths of surgical latex tubing 3/16 inch *(.48 cm)* in diameter with a 1/32 inch *(.08 cm)* wall. The suture is threaded through the tubing and tied. Sutures sheathed in this manner can cause "a severe inflammatory response with reaction both at the site of suture exit from the skin and along the entire length of the suture itself."[2] Skin may become necrotic beneath bolsters if sutures are too tight.

### Retention Suture Bridge

The adjustable retention suture bridge is a device designed to relieve the pressure of retention suture on the skin. A strong plastic truss bridge with a locking capstan located in the middle, this device allows the surgeon to adjust tension over the wound during, and subsequent to, initial placement *(see Fig. 48)*. After the desired number are placed in the wound, a sterile bridge is positioned over each retention suture and the ends passed through the appropriate holes. Because each side has six holes spaced ¼ inch *(.64 cm)* apart, this device is adaptable to patients of all sizes. After the suture is tied loosely over the bridge, the strand is slipped into the raised capstan. Rotation of the capstan permits application of the desired amount of tension. It then is depressed to lock it in place. Tension is easily readjusted to compensate for postoperative wound edema by raising and rotating the capstan. The suture can be loosened and tightened again as the edema subsides. The suture remains elevated away from the skin, but the bridge has contact along its entire 4⅜ inch *(11 cm)* length. Pressure is evenly distributed over the area. The transparency of the bridge allows a full view of the wound. In reported studies, both the suture exit points and the skin underlying the bridge show no inflammatory reaction other than the slight depression of the device on the skin.[3]

## SKIN CLOSURE TAPES

Strong, narrow, sterile strips of tape with an adhesive backing are used for approximating the edges of lacerations and for closing skin following many operative procedures. Clinical evidence indicates that wounds closed with these tapes may develop tensile strength faster than sutured wounds. Stress is uniformly applied to the collagen fibers. Fibrils that cross the wound aid in rapid fiber orientation and increased tensile strength. "The superior resistance to infection of taped wounds as compared to sutured wounds indicates that tape closure of contaminated wounds is a significant clinical tool."[4]

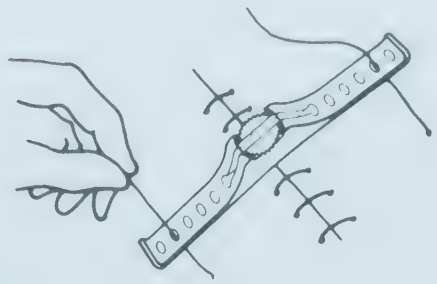
"Adhesive strips relieve the patient of the much feared, but seldom painful, suture removal, but they have two disadvantages: they do not bring deeper tissues together and they do not control bleeding from wound edges."[5] Fine approximation

---

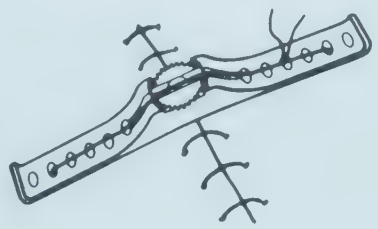
2. Barrer S et al: Ideal laparotomy closure: Comparison of retention sutures with new retention bridging devices, *Am Surg 42:* 582, 1976
3. Ibid
4. Hunt TK, Dunphy JE (ed): *Fundamentals of Wound Management*, New York: Appleton-Century-Crofts, 1979, p. 438
5. Myers MB: Sutures and wound healing, *Am J Nurs 71* (9): 1726, Sept 1971

*Trademark

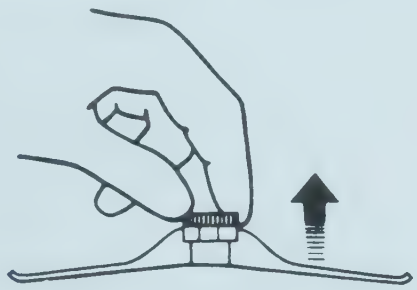
**Fig. 48 Adjustment of retention suture bridge**



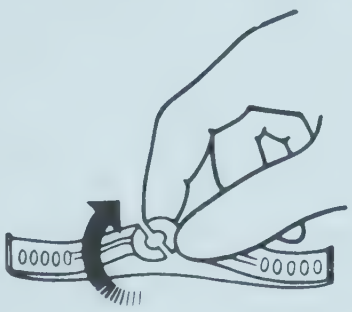
1. Pass the retention suture through holes in bridge.



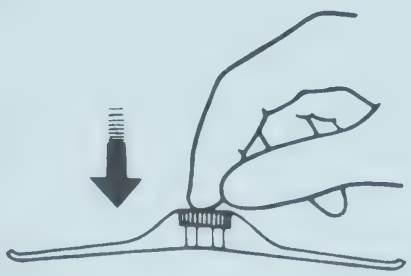
2. Place the suture with tension over slit in capstan and tie.



3. To adjust tension, lift capstan.

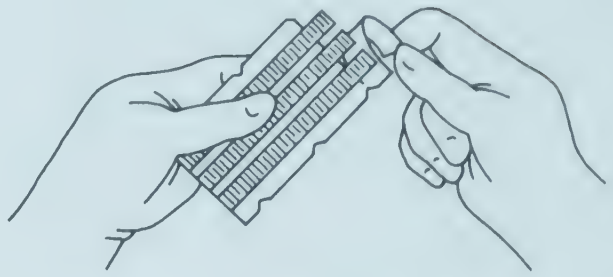


4. Rotate capstan until desired tension is attained.

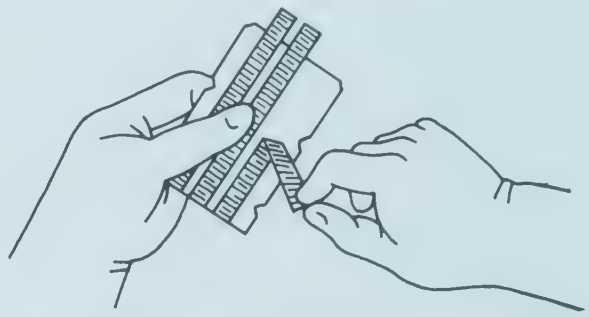


5. To lock, press capstan down into bridge.

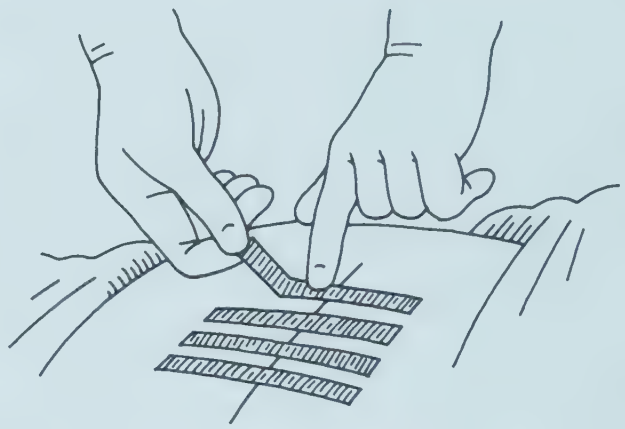
**Fig. 49 Skin closure tapes**



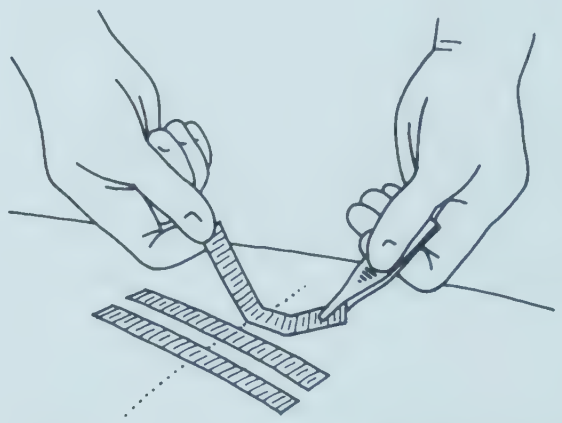
1. Aseptically remove card from sleeve and tear off tab.



2. As needed, peel off skin strips in diagonal direction.



3. Apply additional strips at ⅛ inch intervals, as needed, to complete wound apposition. Make certain that skin surface is dry before applying each skin strip.



4. When healing is judged to be adequate, skin strips may be removed by peeling off each half of a strip up to the wound margin and then gently lifting the strip away from the wound surface.

of the wound with adhesive strips at the time of closure is difficult. Therefore, some surgeons apply them to the skin over a subcuticular closure in lieu of skin sutures at the time of wound closure, or as a primary closure in conjunction with sutures by alternating sutures with strips. Other surgeons suture or staple the skin, but remove the sutures or staples and replace them with skin closure strips on the first to fourth postoperative day. Skin closure tapes are an effective alternative to sutures or staples, particularly when tensile strength and resistance to infection are not critical factors.

CLEARON* skin closures are a woven polypropylene delnet tape coated on one side with a hypoallergenic adhesive mass. The exclusive polypropylene construction is unaffected by moisture. The woven polypropylene delnet is very porous. Porosity ensures adequate wound ventilation, which helps prevent skin maceration. CLEARON skin closures are translucent and nearly invisible when applied to the skin. The surgeon can see how well the wound edges have been coapted and can check the progress of healing. Because of the adhesive quality, use of tincture of benzoin prior to application is not necessary. *Fig. 49* illustrates technics for applying and removing CLEARON skin closures. Five sizes are available.

ETHISTRIP* skin closures are woven rayon acetate tape coated on one side with a hypoallergenic adhesive mass. These closures are opaque. Available in four sizes, they can be used by themselves or to reinforce suture or staple skin closure. They are strong enough to hold the wound until healing takes place, then easily removed without damaging the wound.

## SURGICAL MESH PRODUCTS

Surgical meshes may be used for repair of hernias and other fascial or tissue deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result. Primary closure of large abdominal wall defects under tension usually predisposes to wound necrosis and infection. Insertion of a sheet of mesh to bridge the defect will maintain the position of the viscera within the abdominal cavity until the wound has developed sufficient granulation tissue to avert evisceration. Smaller pieces are used for inguinal or other fascial defects. Surgical mesh for these purposes is made from four different materials: stainless steel, polyester fiber, polypropylene and polyglactin 910. In selection of a fascial substitute, certain fabric characteristics appear to be crucial. The substance should be:

1) Pliable so as to preclude erosion into major structures
2) Inert, thereby avoiding a greater inflammatory response
3) Porous so as to encourage free drainage of exudate and ingrowth of fibroblasts
4) Fiber sufficiently resilient to maintain mesh integrity and thus to offer some potential for permanence.[6]

No significant clinical adverse reactions to the component fibers of meshes available have been reported, but some offer greater advantages than others.

### Surgical Steel Mesh

Surgical steel mesh is composed of woven .003 inch *(0.79 mm)* stainless steel filaments. It is biologically inert with a high degree of tissue acceptability. Steel is opaque to x-ray. This mesh is somewhat inflexible and exhibits handling characteristics that are stiffer than synthetic fabric meshes. It may fragment and cause patient discomfort. Supplied nonsterile, 6 x 12 inch *(15 x 30 cm)* or 12 x 12 inch *(30 x 30 cm)* sheets can be cut to the desired shape or size by the surgeon either before or after steam sterilization. Wire scissors should be used for cutting surgical steel mesh.

### Polyester Fiber Mesh

MERSILENE* polyester fiber mesh is constructed of woven multifilament strands of polyethylene terephthalate, the same material as MERSILENE suture. This mesh affords excellent strength, durability and surgical adaptability, along with maximal porosity for necessary tissue ingrowth. The mesh is approximately 0.010 inch *(0.25 mm)* thick. The 6 x 12 inch *(15 x 30 cm)* or 12 x 12 inch *(30 x 30 cm)* sheets can be cut to desired shape before or after steam sterilization. Provided by ETHICON, INC., as a nonsterile product, sterilization is the sole responsibility of the user. MERSILENE mesh should be sterilized prior to use by conventional steam under pressure at 250°F *(121°C)* for 20 minutes. It may be flash sterilized at 270°F *(132°C)* for 10 minutes. Sterilization by any other means is neither recommended nor endorsed by the manufacturer. The product should be completely removed from

6. Stone HH et al: Management of acute full-thickness losses of the abdominal wall, *Ann Surg 193* (5): 616, May 1981

*Trademark

the clear plastic container prior to sterilization. The mesh may be resterilized not more than one time at 250°F *(121°C)* for 20 minutes.

**Polypropylene Mesh**

PROLENE* polypropylene mesh is constructed of knitted filaments of extruded polypropylene, the identical composition of PROLENE suture. This mesh has high burst strength and high tensile strength. The mesh is approximately 0.027 inch *(0.7 mm)* thick and is undyed *(clear)*. It is supplied sterile in sizes 2½ x 4½ inches *(6 x 11 cm)* and 9 x 14 inches *(23 x 35 cm)*. Unused PROLENE mesh which has been removed from the clear plastic container may be resterilized not more than one time by a conventional steam sterilizing process at 250°F *(121°C)* for 20 minutes. PROLENE mesh should *not* be flash sterilized. Resterilization under any other conditions or by any other means is neither recommended nor endorsed by the manufacturer. If unopened containers are damaged to the extent that product sterility is questionable, mesh should be removed from the package prior to resterilization.

MERSILENE mesh and PROLENE mesh are knitted by a process which interlinks each fiber junction and which provides elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic *(surgical steel)* mesh. The bidirectional elastic property allows adaptation to various stresses encountered in the body. When these meshes are used in infants and children with future growth potential, the surgeon should be aware that these products will not stretch significantly as the patient grows.

These nonabsorbable meshes are used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Both MERSILENE mesh and PROLENE mesh elicit a minimum to slight inflammatory reaction, which is transient, followed by the deposition of a thin fibrous layer of tissue. This can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, so normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. Mesh placed in contaminated wounds should be used with the understanding that it could lead to fistula formation and/or extrusion, and that subsequent infection may require removal of the material. If these products should become stained with blood or soiled, they should not be resterilized or reused in another patient.

*Trademark

**Synthetic Absorbable Mesh**

VICRYL* *(polyglactin 910)* mesh is prepared from a copolymer of glycolide and lactide. It is composed of undyed fiber identical in composition to that used in VICRYL suture. VICRYL mesh is intended for use as a buttress to provide support during the healing process. Being absorbable, it should not be used where extended wound support is required. Significant support is provided for at least 14 days postoperatively. The mesh has approximately 20 percent of its initial strength after 21 days. The absorption of VICRYL mesh is minimal until about 42 days. Absorption is essentially complete between 60 and 90 days. This mesh may act as a scaffolding for ingrowth of connective tissue. It is supplied sterile in 10½ x 13½ inch *(26.5 x 34 cm)* and 5 x 6½ inch *(13 x 17 cm)* sheets. It cannot be resterilized. The safety and effectiveness of VICRYL mesh in neural and cardiovascular tissue has not been established.

**Security of Mesh Products**

For the secure placement of all types of meshes, sutures should be placed ¼ to ½ inch *(6.5 to 12.5 mm)* apart at a distance of approximately ¼ inch *(6.5 mm)* from the edge of the mesh. Nonabsorbable meshes should be secured with nonabsorbable sutures preferably of the same material as the mesh. VICRYL mesh may be secured with either absorbable or nonabsorbable sutures.

Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound, starting on one side of the mesh. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away, leaving approximately ¼ inch *(6.5 mm)* of mesh extending beyond the suture line.

## TAPES

**MERSILENE* Polyester Fiber Strip**

Flat tape, rather than a large size suture, may be advantageous for ligation, repair and/or support in some selective operative procedures. A five

millimeter width of a double thickness of MERSILENE polyester fiber is available in strips both with and without needles.

Incompetence of the cervix is a condition characterized by the habitual premature, spontaneous abortion of the fetus. A ligature is placed around the cervix in a collar-like fashion drawn tight, and either sutured together or tied closed. Swaged large blunt needles frequently are used to place the flat MERSILENE strip around the cervix by weaving the strip in and out of the mucosa. The flatness of the strip will not cut or damage the wall of the cervix, if properly placed.

MERSILENE strip provides a wide band of strong material for repair and support of the rotator cuff in the shoulder. It is available attached to a heavy reverse cutting needle specifically designed for orthopaedic surgery. However, some orthopaedic surgeons prefer the blunt needles as used for the incompetent cervix.

### Umbilical Tape

Umbilical tape is a white woven cotton ligature, ⅛ inch or ¼ inch *(.32 or .64 cm)* wide, that is strong enough to tie off the umbilical cord of the newborn infant. This was its original use; hence the source of its name. It is frequently used in pediatric and cardiovascular operative procedures to suspend small structures and vessels.

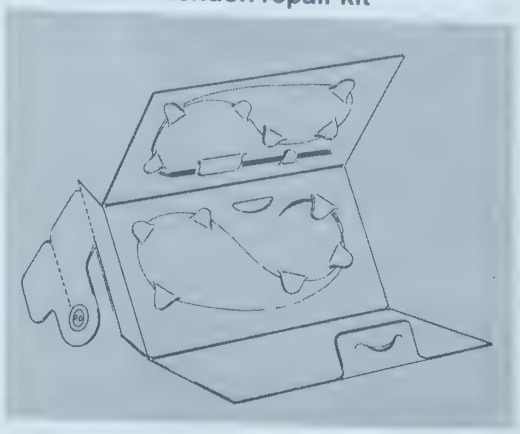
Umbilical tape easily absorbs blood when used in an area of gross bleeding. An ⅛ inch *(.32 cm)* tape with a radiopaque thread woven into the entire length of the fabric is available. If inadvertently lost or left in the wound, this tape can be located on x-ray.

## TENDON AND LIGAMENT REPAIR

### Tendon Repair Kits

A concept to meet the suture needs in the Bunnell tendon repair technic is illustrated in *Fig. 50.* The foldout inner packet contains a surgical stainless steel suture, 14 inches *(35 cm)* long, double-armed with straight cutting needles. Within the same packet is an eight inch *(20 cm)* surgical steel suture loop attached to a curved TAPERCUT* surgical needle. Also included is a polypropylene button. These kits are especially designed for surgeons who favor the Bunnell pull-out suture method of tendon repair. The packet was designed to prevent kinks in the wire. A barbed suture also is available in a kit for alternate methods of tendon repair. Extra sterile polypropylene buttons also are available separately, three to a packet.

Fig. 50 ETHICON* tendon repair kit



### Anterior Cruciate Ligament Repair

Several technics are used to repair and/or reconstruct the anterior cruciate ligament in the knee. Often the surgeon will make a drill hole in the femur and pull the sutures, which are sutured to the ligament, through the hole. The strands must be tied simultaneously to adjust tension properly. To determine the corresponding strands to tie together, a packet is available with three 30 inch *(75 mm)* multi-colored strands of ETHIBOND* polyester sutures, size 0, each swaged to a ½ circle reverse cutting needle. The green, light green and white colors help keep the sutures in proper orientation.

Use of PDS* *(polydioxanone)* synthetic absorbable sutures as an internal stent in repair of the anterior cruciate ligament is gaining acceptance, but clinical experience is insufficient to recommend this technic.

## TEMPORARY CARDIAC PACING WIRE

After open heart surgery, patients occasionally experience temporary cardiac arrhythmias or low cardiac output syndromes during the first two weeks postoperatively that cannot be adequately controlled with medication. In preparation for this possible occurrence, the cardiovascular surgeon generally implants two to four temporary pacing wires to the surfaces of the heart. These are used to pace *(stimulate)* or monitor the electrical conduction system of the heart.

The ETHICON* temporary cardiac pacing wire is constructed using a core of size 2-0 multifilament stainless steel, 24 inches *(60 cm)* in length, with a curved needle swaged to one end and a straight Keith needle swaged on the other end. The stain-

*Trademark

less steel is coated with a layer of blue polyethylene along its length, leaving a 2½ inch *(6 cm)* section of uninsulated wire adjacent to the curved needle. Care should be taken to avoid disruption of the polyethylene coating or damage to the conductive wire by manipulating with instruments or when tying knots. The uninsulated distal end is sutured to the myocardium using the curved needle. The Keith needle is then passed through the chest wall and the pacing wire firmly attached to the skin. The Keith needle is snapped at the scored point, eliminating the need for any special tools to cut the needle. After breaking, the Keith needle is ready for attachment to an external pacing unit or monitor *(see Fig. 51)*.

The temporary cardiac pacing wire is intended for *temporary* cardiac pacing or monitoring. The availability of four different needle codes make the pacing wire appropriate for all pediatric and adult patients, and satisfies individual surgeon preferences. The pacing wire is generally removed 10 to 14 days postoperatively. When permanent cardiac pacing or monitoring is required, the use of the temporary cardiac pacing wire is contraindicated.

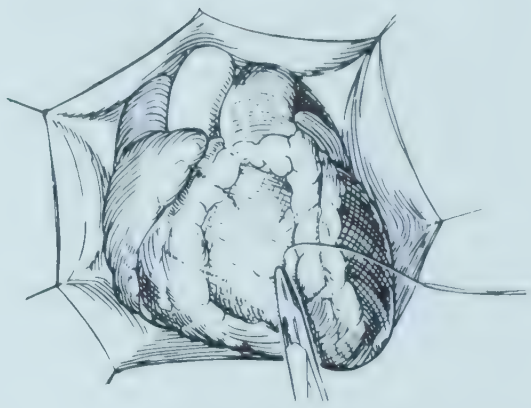
After the chest is closed, identical appearing pacing wire/s implanted in the atrial myocardium is difficult to distinguish from the one/s in the ventricle. A MULTI-STRAND packet is available that contains two wires, one light blue and one dark blue for color differentiation by location.

## VISIBILITY BACKGROUND MATERIAL

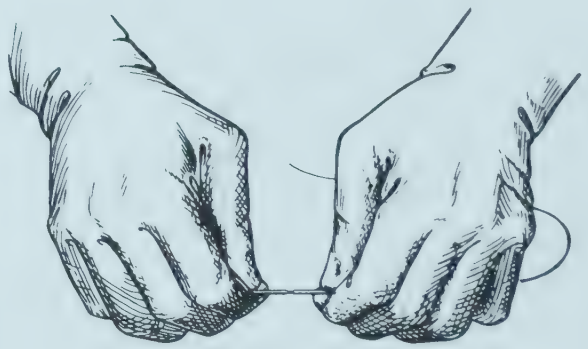
Microsurgeons use visual contrast swatches under a nerve or vessel to blot out tissue background and isolate the structure for easy viewing under the operating microscope. Packets of sterile visibility background materials are available for this purpose. Each packet contains two ¾ x 1½ inch *(21 x 42 mm)* polyethylene swatches, one yellow and one blue.

*Trademark

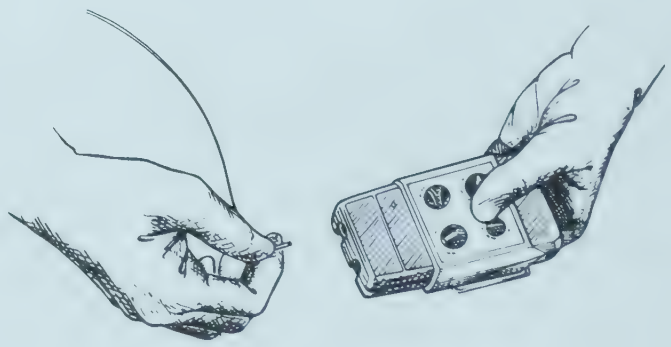
**Fig. 51 ETHICON* temporary cardiac pacing wire**



1. Distal end of temporary cardiac pacing wire is attached to myocardium as indicated by surgical circumstance and the preference of the operator.



2. Straight needle is snapped at scored point after having been passed through chest wall.



3. Proximal end of temporary cardiac pacing wire is ready to connect to temporary pacing unit or monitoring unit.

SECTION IX

# Research and Development at ETHICON, INC.

Operative procedures undergo constant change and improvement. So, too, must wound closure products be improved continuously if they are to keep pace with the giant strides made by modern surgeons. At ETHICON, INC., the search is unending for better sutures, needles and mechanical devices to complement the surgeon's skills. Unceasing efforts are made to provide nurses with convenient packaging and presentation of wound closure products for ease of handling. Every improvement is for the ultimate benefit of the patient.

Since the development of nylon fibers in the 1940s, scientists have made new polymers, such as polyethylene terephthalate, polypropylene and the copolymer of glycolide and lactide, to obtain materials with properties not available from natural sources. These developments led to new suture materials: MERSILENE* polyester fiber suture, PROLENE* polypropylene suture, VICRYL* *(polyglactin 910)* suture and PDS* *(polydioxanone)* suture.

All new materials must be extensively tested in animals for safety and efficacy before clinical trials in humans can be initiated. Similar testing is generally required even when changes are made in minor ingredients, e.g., coating or dye, of known suture materials.

## SAFETY STUDIES

The ETHICON Research Foundation was established for the sole purpose of testing the safety and efficacy of new sutures and wound closure products. The testing noted below is representative of the intensive and extensive evaluation by ETHICON, INC., for all new materials that are to be implanted in the body. These studies require time and money. Results of animal studies precede clinical trials with new materials.

### Chronic Toxicity

Sutures are implanted in two species of animals at dosage levels that are far above the estimated human use level based upon the body weight. Critical clinical parameters are measured continuously throughout the many months of the study. This is followed by necropsy examination and histopathologic examinations of the tissue.

### Acute Toxicity

Sutures, as well as the suture components, are implanted in rats and mice at dose rates more than 100 times the estimated human use level. The animals are evaluated by clinical observations, body weight before and after implantation, and gross observations at necropsy.

### Absorption and Excretion of Carbon-14 Labeled Suture *(Absorbable Materials Only)*

Samples of the absorbable suture material are prepared by an elaborate, sophisticated synthesis in which the carbon atoms are replaced by radioactive carbon-14. These radioactively labeled sutures are implanted in rats. The excretion profile is determined by evaluating the carbon-14 activity in the urine, feces and exhaled carbon dioxide for the entire absorption period. Animals euthanatized at predetermined intervals and the carbon-14 activity recovered from the implant sites provides a direct estimation of the amount absorbed. In addition, the radioisotope activity from the body organs is determined. The analysis is designed to evaluate:

1) Whether the suture is completely absorbed
2) Whether the metabolic products of the degradation of the absorbable suture are readily excreted
3) The route for the excretion of the metabolic products.

### Teratology Studies *(Absorbable Sutures Only)*

Sutures are implanted in rats and rabbits at many times the estimated human dosage. The animals are bred following implantation. Suture absorption and systemic levels are highest during the fetal organogenesis. Following euthanasia, just prior to birth, fetal development is evaluated for signs of abnormalities.

### Tumorigenicity

The tumorigenic potential of sutures is evaluated in rats at a dosage far above the estimated human dosage. Approximately 400 rats are used, including controls. The rats are observed daily for clinical signs, throughout their entire life. Complete necropsies are performed. All major organ systems, implant sites and lesions are examined histopathologically.

*Trademark

### Allergenicity and Immunogenicity Studies

The sutures are implanted in guinea pigs. Post-implantation investigations of humoral antibody response are studied and a series of assays conducted to evaluate cell mediated immunity. Any evidence of sensitization or allergenicity is observed and noted.

### Pyrogenicity

The suture material, at a high dose level, is extracted and injected into rabbits using the standard United States Pharmacopoeia method. The extract is also tested via an *in vitro* test. Pyrogenicity or nonpyrogenicity is determined.

### Breaking Strength Retention

Various sizes of sutures are implanted subcutaneously in rats. Following *in vivo* residence for periods of 1, 2, 3, 4, 6 and 8 weeks, the suture strands are recovered, and tested on an Instron Universal Testing Unit. The average breaking strength remaining is calculated as the percentage of the original unimplanted strength.

### Breaking Strength Retention–Infected Wound

A similar study to the one described above is carried out using sutures that have been purposely contaminated. Infection at the site of implantation and its effect on breaking strength retention is determined.

### Tissue Retention–Absorption

The suture is tested in rats. Over 3,400 implant sites are evaluated at various post-implantation periods. Tissue reaction is evaluated by histologic analysis. Absorption, if any, is determined by measuring microscopically the area remaining of cross sections of the suture from the implant site. Tissue response and suture absorption rate are also studied in the ocular tissue of rabbits.

### Surgical Efficacy

The surgical efficacy of the suture material is demonstrated in animals in numerous separate experiments evaluating use in a wide range of surgical procedures.

## RESULTS

The results of these extensive animal studies are evaluated by ETHICON, INC., scientists and reviewed by independent experts. If our scientists, independent experts and the F.D.A. agree that the suture material is safe and nontoxic and was effective in adequately maintaining wound support, permission is granted for ETHICON, INC., to conduct clinical trials in humans.

F.D.A. approval for every material is based upon proof of safety and efficacy for animals and demonstrated clinical utility and safety.

Such careful and exhaustive testing is necessary to be absolutely certain that every new product is safe and effective. ETHICON researchers are continuing to extensively evaluate, in the same manner, the new wound closure products of the future.[1]

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1. Levy AJ: Testing new suture materials, *Point of View 19* (2): 14-15, April 1982

SECTION X

# Product Terms and Trademarks of ETHICON, INC.

**ABSOLOK* Ligating Appliers** ETHICON trademark for instruments used for applying ABSOLOK* ligating clips.

**ABSOLOK* Ligating Clips** ETHICON trademark for absorbable ligating clips, molded from violet polydioxanone polymer, for use as absorbable ligatures to ligate arteries, veins, nerves and other small structures.

**ABSOLOK* Multiple Clip Applier** ETHICON trademark for disposable applier loaded with absorbable polydioxanone polymer clips for multiple ligations.

**Absorbable Suture** A material which is attacked, broken down and eventually absorbed by either hydrolysis *(synthetic absorbable sutures)* or digestion by lysosomal enzymes elicited by white blood cells *(surgical gut and collagen)*.

**approximate** Bring together two sides or edges.

**ATRALOC* Surgical Needles** ETHICON trademark for eyeless needles permanently attached *(swaged)* to suture strands.

**BIOMER* Segmented Polyether Polyurethane Solution** ETHICON trademark for solution used for research purposes.

**Blunt Point Needle** Specially designed needle which has a rounded tip; useful in suturing friable tissue such as liver and kidney. Blunt point needle also swaged to flat ribbon of MERSILENE* polyester fiber for encircling and closing the incompetent cervix.

**Bone Wax** Mixture of beeswax and isopropyl palmitate used to achieve local hemostasis of bone by acting as a mechanical barrier.

**B & S gauge** Brown and Sharpe gauge commonly used in hospitals to identify wire diameter. ETHICON* stainless steel suture products are labeled with both B & S gauge and U.S.P. size.

**buried suture** Any stitch made and tied so that it remains completely under skin surface.

**Calcified Coronary Needle** A TAPERCUT* surgical needle with a slim taper ratio for significant ease of penetration when suturing tough, calcified or atherosclerotic tissue.

**capillary** Characteristic of suture materials that allows passage of tissue fluids along strand.

*Trademark

**Cardiovascular Sutures** Product line of swaged sutures designed to meet the specific needs of heart and blood vessel surgery.

**CARGILE* Membrane** ETHICON trademark for membrane prepared from the cecum of the ox to cover surfaces from which peritoneum has been removed.

**catgut** Outmoded term for surgical gut.

**Chromic Surgical Gut** Absorbable suture which has been treated to resist digestion by lysosomal enzymes *(Type C)*.

**CLEARON* Skin Closures** ETHICON trademark for sterile adhesive polypropylene strips used for skin closure.

**Coated TYVEK®** Material used for overwrap of some sterile wound closure products.

**Coated VICRYL* (polyglactin 910) Suture** ETHICON trademark for synthetic absorbable suture extruded from a copolymer of glycolide and lactide and coated with a mixture of polyglactin 370 and calcium stearate.

**cobalt 60** Source of gamma rays used by ETHICON INC., to sterilize some suture materials. Cobalt 60 also is used in hospitals to treat some patients who have cancer.

**COLLAGEN PURE** Process of chemical purification in the cleaning of intestines to remove noncollagenous proteins.

**Collagen Suture** Absorbable suture made of beef tendon by an extrusion process.

**Compound Curved Needle** A needle that incorporates two curvatures in one needle: a tight curve at the tip, a more gradual curve through the body of the needle. It is used for precise positioning of sutures for corneal/scleral closure.

**contaminate** To cause a sterile object or surface to become unsterile.

**continuous suture technic** One strand passed back and forth between the two edges of the wound to close a tissue layer; tied only at each end of the suture line.

**CONTROL RELEASE* Needle or Needle Suture** ETHICON trademark for swaging concept which permits fast and controlled separation of the needle from the suture material.

**Conventional Cutting Needle** A needle with triangular point and two cutting edges along inner curvature of needle body.

**Corneal Beaded Retraction Suture** A swaged suture strand with a small bead of epoxy used to elevate cornea for placement of intraocular lens.

**Cuticular Sutures** Product line designed for routine skin closure.

**dead space** Pockets left in a tissue layer when tissues are not in close approximation.

**decontamination** A process used to destroy microorganisms known or thought to be present on a surface or object.

**dehiscence** Total or partial separation of wound edges.

**Dermal Suture** Degummed and purified twisted silk encased in nonabsorbable coating of tanned gelatin.

**Dispenser Boxes** Gravity-fed vertical or horizontal boxes that readily dispense wound closure products. Labels on boxes include all product information.

**Do Not Resterilize** On a suture packet label, this phrase means that the packet cannot be subjected to steam under pressure without potential damage to contents or packet.

**double-armed suture** Suture strand with a needle swaged at each end.

**EASY ACCESS* Packaging** ETHICON trademark for patented delivery system that presents the needle in position for immediate arming in the needleholder as soon as the primary packet is opened.

**enzyme** Complex substance within tissue cells. One of the capabilities of enzymes is breaking down and digesting surgical gut.

**E-Pack** Single overwrap containing organizers with multiple ETHICON foil suture packets. Each E-Pack is customized with choice of sutures for specific procedure.

**ETHIBOND* Polyester Suture** ETHICON trademark for polyester fiber suture coated with polybutilate.

**ETHICON*** The brand name for products manufactured by ETHICON, INC. The name was first used in 1926 by Johnson & Johnson.

**ETHIFLEX* Polyester Fiber Suture** ETHICON trademark for sutures made of polyester fibers impregnated with TEFLON®.

**ETHILON* Nylon Suture** ETHICON trademark for sutures made of monofilament nylon.

**ETHI-PACK* Pre-cut Suture** ETHICON trademark for pre-cut strands of nonabsorbable sutures with and without needles, sterile and nonsterile.

**ETHISTRIP* Skin Closures** ETHICON trademark for multi-use sterile adhesive strips used for skin closure.

**ethylene oxide gas** Chemical agent used to sterilize some suture materials and to resterilize suture packets.

**evisceration** Protrusion of bowel through separated edges of abdominal wound closure.

**expiration date** Date on a suture packet representing the time through which satisfactory stability studies have been carried out. As such studies are continued, the expiration date may be extended.

**extrusion of knot** Because sutures are "foreign bodies" in human tissues, enzymes in the cells act to wall-off nonabsorbable suture. Rarely the body will continue its attempt to be rid of nonabsorbable suture. Months or even years after surgery, a knot or knots of nonabsorbable suture may work their way to skin surface. This is known as knot extrusion or "spitting".

**fascia** Areolar tissue layers under the skin *(superficial fascia)* or fibrous tissue between muscles and forming the sheaths of muscles or investing other structures such as nerves or blood vessels *(deep fascia)*.

**Fascia Lata** Strips of fascia obtained from the fibrous connective tissue which covers thigh muscles of beef cattle.

**F.D.A.** Abbreviation for Federal Food and Drug Administration. F.D.A. is charged with responsibility of enforcing laws and regulations relating to drugs, devices and cosmetics. Wound closure materials fall in the category of *devices* and are bound by F.D.A. regulations.

**Gastrointestinal Sutures** Product line designed specifically for use in bowel and stomach surgery.

**gauge** Term used to express diameter of suture strand.

**General Closure Sutures** Product line useful in closing incisions, particularly of the abdominal wall.

**hemostasis** Stopping blood flow from a vessel.

**hydrolysis** Chemical process whereby a compound or polymer reacts with water to cause an alteration or breakdown of the molecular structure. Synthetic absorbable sutures are degraded *in vivo* by this mechanism.

**infection** Invasion of body tissue by disease producing organisms.

**INTERLOCK* Locking Feature** ETHICON trademark for the special locking feature of the ABSOLOK ligating clip to securely hold the clip on the desired tissue or vessel.

*Trademark

**interrupted suture technic** Single stitches separately placed, tied and cut.

**Keith Needle** Straight needle with cutting edges. Named for a Scottish surgeon, Dr. Thomas Keith, who made the needle popular.

**kink** Undesirable deformation of a strand, such as a sharp bend in wire.

**knot tying** Technic for securing suture in proper place. The standard technic of flat and square ties may require additional throws if indicated by variables inherent in the material itself, surgical circumstance or the experience of the surgeon.

**LABYRINTH Package** A unique package manufactured by ETHICON, INC., that dispenses straight, kink-free, pre-cut nonabsorbable sutures one strand at a time.

**Lacrimal Stent** Medical grade silicone tubing attached to two stainless steel probes for use in reconstruction of the lacrimal outflow system.

**LIGACLIP* Ligating Appliers** ETHICON trademark for instruments used for applying LIGACLIP* ligating clips.

**LIGACLIP* Ligating Clips** ETHICON trademark for tantalum, titanium or stainless steel clips used to ligate arteries, veins, nerves and other small structures.

**LIGACLIP* Ligating Clip Removers** ETHICON trademark for instrument used to remove LIGACLIP ligating clips as indicated by surgical circumstance.

**LIGACLIP* Multiple Clip Applier** ETHICON trademark for disposable applier loaded with stainless steel clips for multiple ligations.

**LIGAPAK* Dispensing Reel** ETHICON trademark for disc-like plastic reel which contains and dispenses ligating material.

**LIGAPAK* Ligature** ETHICON trademark for a length of suture material wound on a reel, primarily used for ligating.

**ligating reel** A tube, plastic disc or other device from which continuous ligating material is unwound as blood vessels are tied.

**ligature** Strand of material used to tie off a blood vessel.

**Looped Suture** Single strand of suture material with both ends swaged to a single needle.

**MERSILENE* Polyester Fiber Mesh** ETHICON trademark for machine-knotted fabric which is porous and permeable for ingrowth of tissue cells. It is used to reinforce blood vessel defects, abdominal wall and diaphragm defects, and in some plastic and reconstructive operations.

**MERSILENE* Polyester Fiber Strip** ETHICON trademark for flat band 5 mm wide. Useful as an encirclage suture around the cervix in some patients diagnosed as having an incompetent cervix, or for repair and support of rotator cuff in the shoulder.

**MERSILENE* Polyester Fiber Suture** ETHICON trademark for nonabsorbable suture material made of polyester polymer.

**MICRO-POINT* Spatula Needle** Side-cutting needles produced by ETHICON, INC., which are thin and flat in profile and specially honed for exceptional sharpness.

**MICRO-POINT* Surgical Needle** ETHICON trademark for needles which are individually honed and polished to extremely fine finish and sharpness. Designed to meet exacting requirements in ophthalmic surgery.

**Microsurgery Sutures** Product line for surgery in which an operating microscope must be used to visualize the very small structures involved, e.g., blood vessels and nerves.

**mil** A unit of linear measurement, equivalent to 0.001 inch. Frequently used to express wire diameter of surgical needles.

**Modular Suture Storage Rack** Plastic modules of expandable interlocking units that provide neat, convenient storage of ETHICON suture dispenser boxes.

**monofilament** Strand consisting of a single thread.

**multifilament** Strand made of more than one thread held together by twisting or braiding.

**MULTI-STRAND Package** Multiple swaged sutures of one type supplied in one packet.

**needle** Instrument used to carry strand of suture material through tissue.

**needleholder** Surgical instrument used to hold a curved needle during suturing.

**needle-suture junction** Point at which eyeless needle and suture strand are joined.

**NUROLON* Braided Nylon Suture** ETHICON trademark for a multifilament braided nylon suture material.

**Neurosurgery Sutures** Product line of swaged sutures particularly well suited to surgery of the brain and nervous system.

**Nonabsorbable Suture** Material which tissue enzymes cannot dissolve. Remains encapsulated

*Trademark

when buried in tissues and is removed postoperatively when used as skin suture.

**noncapillary** Characteristic of nonabsorbable sutures wherein their nature or specific processing meets tests that establish them as resistant to "wicking" transfer of body fluids.

**nylon** Synthetic suture material made of polyamide polymer.

**OB-Gyn Sutures** Product line containing needle-suture combinations particularly useful in obstetric and gynecological operations.

**Ophthalmic Sutures** Product line of ultra-fine needles attached to small gauge suture materials to meet exacting needs in ophthalmic surgery.

**Orthopaedic Sutures** Product line of sutures attached to needles appropriate for orthopaedic surgery.

**overwrap** The exterior packet which protects the sterility of inner suture packet.

**Package Insert** Complete product information inserted in each box of wound closure products, as required by F.D.A.

**PDS* (polydioxanone) Suture** ETHICON trademark for monofilament synthetic absorbable suture prepared from the polyester poly (d-dioxanone).

**PERMA-HAND* Silk Sutures** ETHICON trademark for sutures specially processed to remove gum and impurities from raw silk before braiding into strands.

**Plain Surgical Gut** Absorbable suture untreated to resist digestion *(Type A)*.

**Plastic Surgery Sutures** Product line specifically designed to assist the surgeon in obtaining excellent cosmetic results in plastic and reconstructive surgery.

**pledgets** Small pieces of TEFLON® felt used as a buttress under sutures when there is a possibility of friable tissue tearing in cardiovascular surgery.

**Polybutilate** A nonabsorbable nonreactive polymer lubricant developd by ETHICON, INC., as a coating for ETHIBOND sutures.

**polyester fiber** Synthetic material made of a polyester polymer of polyethylene terephthalate.

**polypropylene** Synthetic material of an isotactic crystalline stereoisomer of a linear hydrocarbon polymer containing little or no unsaturation.

**Polypropylene Buttons** Synthetic material made into buttons. Useful in orthopaedic procedures such as tendon repair. Sutures are tied over buttons to relieve underlying skin of excessive pressure.

**Precision Cosmetic Needle** Conventional cutting needles specially polished and carefully honed for aesthetic plastic surgery.

**Precision Point Needles** Reverse-cutting needles specially polished and carefully honed for plastic surgery.

**Pre-cut Sutures** Strands of suture material packaged with several strands cut into 18, 24, or 30 inch lengths.

**Primary Packet** Suture packet which contains the sterile strand/s.

**primary wound closure** Sutures or staples used to approximate wound edges.

**Product Code** Numbers or combination of letters and numbers which identify a specific product.

**PROLENE* Polypropylene Mesh** ETHICON trademark for mesh made of polypropylene which is knitted by a process which interlinks each fiber juncture. It is used for the repair of hernias and tissue deficiencies.

**PROLENE* Polypropylene Suture** ETHICON trademark for synthetic nonabsorbable suture material made of monofilament polypropylene.

**PROXIMATE* Flexible Linear Stapler** ETHICON trademark for internal disposable stapler with a flexible coupling between handle and jaws, used for approximating tissues in alimentary tract and thoracic cavity.

**PROXIMATE* ILS Intraluminal Stapler** ETHICON trademark for disposable circular anastomotic stapler for use throughout alimentary tract for end-to-end, end-to-side or side-to-side anastomoses.

**PROXIMATE* Linear Stapler** ETHICON trademark for rigid disposable stapler that delivers straight row of double staggered staples to approximate tissues in alimentary tract and thoracic cavity.

**PROXIMATE* Plus Skin Stapler** ETHICON trademark for disposable skin stapling unit preloaded with 316L stainless steel staples.

**PROXIMATE* PSD Purse String Device** ETHICON trademark for disposable device used to facilitate placement of purse-string sutures in anastomotic procedure in conjunction with the ILS stapler.

**PROXIMATE* QUANTUM Skin Stapler** ETHICON trademark for disposable skin stapler with rotating head, precocking feature and coated staples.

*Trademark

**PROXIMATE* Skin Staple Extractor** ETHICON trademark for disposable extractors used to remove skin staples.

**PROXIMATE* II Skin Stapler** ETHICON trademark for compact size disposable skin stapler.

**PROXIMATE* TMD Tissue Measuring Device** ETHICON trademark for disposable device used in conjunction with ILS and linear staplers to measure tissue thickness, and with ILS stapler to measure organ diameter to achieve a proper intestinal anastomosis.

**rate of absorption** Rate of absorption of surgical gut and collagen depends on the relative resistance of the strand to digestion by tissue enzymes. Coated VICRYL suture and PDS suture are absorbed by a slow hydrolysis. How quickly the suture will be absorbed is influenced by type of material, type of tissue in which it is implanted, presence of infection or "tissue hunger" diseases such as cancer, malnutrition, prolonged fever.

**Resterilization Service** Service offered hospitals by suture manufacturers in which unopened and undamaged suture packets may be returned for reoverwrapping and resterilization. R/S is symbol for ETHICON resterilization service.

**Retention Suture Bolsters** Lengths of surgical latex tubing used to sheath retention sutures to prevent cutting the skin.

**Retention Suture Bridge** A plastic device designed for adjustable tension postoperatively on retention sutures.

**Retention Sutures** Product line of heavy strands of nonabsorbable material swaged to large needles designed to reinforce the primary wound closure when unusual stress on the suture line is anticipated in the postoperative period. Also called "stay" or "tension" sutures.

**Reverse Cutting Needle** Needles produced by ETHICON, INC., which have triangular shape throughout their entire length. Cutting edges are along outside needle curvature.

**Ribbed Needle** Needles manufactured only by ETHICON, INC., with longitudinal grooves on inner and outer curvatures. Ribs are counter-directional to serrations in needleholder jaw and help to stabilize needle in holder.

**SABRELOC* Spatula Needle** ETHICON trademark for needle specially designed for ophthalmic surgery. Side-cutting spatula-shaped edges separate the ultra-thin layers of scleral or corneal tissue without cutting through.

**secondary suture line** Retention sutures placed about 2″ away from wound edges to reinforce primary closure and protect it from stress.

**Side-flattened Needles** Configuration of stainless steel alloy needles designed to increase strength to reduce bending when penetrating vascular prostheses or calcified tissues.

**Stainless Steel Mesh** Surgical grade stainless steel mesh used to reinforce tissue defects.

**Standard Length Suture** Absorbable suture strand 54″ in length or 60″ nonabsorbable strand.

**staple** Device used to approximate tissue.

**stapler** Instrument used to insert staples into tissue.

**sterile** Free of living microorganisms *(bacteria and their spores, viruses, etc.)*

**sterile barrier** Invisible line of demarcation between the sterile and nonsterile.

**sterile field** Specific limited area covered by sterile drapes during the operation.

**Sterile-Pack Dry** ETHICON sutures in foil packets within foil-plastic overwraps. Supplied in boxes, sterile and ready to use.

**sterile technic** Collectively, all the efforts made and procedures followed to exclude microorganisms from the operative wound.

**sterilization** Process by which all living microorganisms on an object are destroyed.

**SUPER-SMOOTH Finish** An exclusive process that provides a finish on most ETHICON needles that permits the needles to penetrate and pass through the toughest tissue with minimal resistance.

**Surgical Gut** Absorbable suture made from serosal layer of beef intestine or submucosal layer of sheep intestine.

**Surgical Stainless Steel Suture** Nonabsorbable suture made of 316L steel alloy.

**SURGISET* Emergency Suture Assortment** ETHICON trademark for cuticular sutures supplied for convenient use in physician's office or emergency department.

**SUTUPAK* Pre-cut Sterile Sutures** ETHICON trademark for packet containing multiple pre-cut strands of suture material without needles, sterile and ready for immediate use.

**suture** Material used to approximate *(sew)* tissues or tie off blood vessels.

*Trademark

**suture book** Sterile towel folded by the scrub nurse and used to contain multiple sutures.

**suture routine** The surgeon's usual preference in suture materials and sizes.

**Swaged Suture** A strand of material with eyeless needle attached by manufacturer.

**TAPERCUT* Surgical Needle** An ETHICON trademark for a needle which has a triangular tip with three sharp cutting edges. The remainder of the needle has a gradually tapered body.

**Taper Point Needle** The body of the needle gradually tapers to a sharp point that makes the smallest possible hole in tissue.

**Temporary Cardiac Pacing Wire** Multifilament stainless steel coated with polyethylene, with curved needle swaged to the distal end and a scored straight needle to the other, for use in temporary cardiac pacing or monitoring.

**Tendon Repair Suture** An ETHICON product which includes, in one packet, a pull-out wire set and a polypropylene button. These components are appropriate for use in the Bunnell technic of tendon repair.

**tensile strength** Amount of tension or pull expressed in pounds which a suture strand will withstand before it breaks.

**TG Needles** Series of spatulated needles specially honed to a long, sharp, slim tip.

**ties (ligatures)** Strands of material used to tie and close the ends of severed blood vessels. FREE or FREEHAND: single strands used as individual ties. CONTINUOUS: long strands unwound from a reel or other device as blood vessels are tied. SUTURE LIGATURE: strand on a needle used to transfix *(suture)* a large blood vessel closed for security against knot slippage. STICK TIE: in some ORs, a suture ligature. In others, a single strand handed to surgeon for ligating with a hemostat clamped on one suture end. TRANSFIXION SUTURE: suture ligature.

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*Trademark

**TRU-CHROMICIZING** The ETHICON process of bathing each ribbon of surgical gut in a chromium salt solution before spinning into strands to provide uniform controlled absorption.

**TRU-GAUGING** The ETHICON process to assure uniform diameter and uniformly higher tensile strength of surgical gut.

**TRU-PERMANIZING** The ETHICON process of treating silk for noncapillarity.

**tubing fluid** Solution inside packets of surgical gut and collagen. Its purpose is to maintain material *(and needle, if attached)* in optimum condition for immediate use on withdrawal from the packet.

**Umbilical Tape** Woven cotton tape, classified as a ligature, used as a gentle means of retracting vessels in cardiovascular and pediatric surgery.

**Urological Sutures** Product line designed to meet the needs peculiar to surgery performed by urologists. Features 5/8 circle needle which turns out of tissue quickly.

**U.S.P.** United States Pharmacopeia. An official compendium in which standards are set forth and ranges defined for purity, strength and dosage of drugs. Sanctioned by an act of Congress, U.S.P. is the official reference of the Food and Drug Administration when this agency tests drugs.

**VICRYL* (polyglactin 910) Mesh** ETHICON trademark for mesh prepared from a copolymer of glycolide and lactide. An absorbable material, it is intended for use as a buttress to provide temporary support during the healing process.

**VICRYL* (polyglactin 910) Suture** ETHICON trademark for synthetic absorbable suture extruded from a copolymer of lactide and glycolide.

**Visibility Background Material** Polyethylene swatches used for visual contrast under a nerve or vessel during microsurgery.

**VISI-BLACK* Surgical Needles** ETHICON trademark for surgical needles with a black surface finish to enhance visibility at the operative site.

**wound disruption** Separation of wound edges.

SECTION XI

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SECTION XII

# Sterile Sutures: Tensile Strength and Metric Measures

## Sterile Sutures/Knot Pull Tensile Strength Chart

| | NONABSORBABLE | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | CLASS I | | | | | | CLASS II | | | | CLASS III | | | |
| | USP REQUIRED | | | | | | NYLON | | | | | | | | STEEL | | |
| USP SIZE | DIAMETER (MIL.) MIN | DIAMETER (MIL.) MAX. | KNOT PULL LBS | SILK BRAIDED | ETHIBOND* BRAIDED | MERSILENE* BRAIDED | ETHILON* MONO | NUROLON* BRAIDED | PROLENE* MONO | USP KNOT REQ LBS | COTTON TWISTED | DERMAL TWISTED | LINEN TWISTED | USP KNOT REQ LBS | MONO | MULTI | B&S GAUGE |
| 11-0 | .4 | .75 | .01 | — | — | — | .01 | — | .01 | — | — | — | — | — | — | — | — |
| 10-0 | .8 | 1.1 | .04 | — | — | — | .07 | — | .07 | .03 | — | — | — | .11 | — | — | — |
| 9-0 | 1.2 | 1.5 | .08 | — | — | — | .11 | — | .13 | .05 | — | — | — | .13 | — | — | — |
| 8-0 | 1.6 | 1.9 | .13 | .20 | — | — | .20 | — | .20 | .09 | — | — | — | .24 | — | — | — |
| 7-0 | 2.0 | 2.7 | .24 | .35 | .50 | — | .40 | .40 | .40 | .13 | — | — | — | .35 | — | — | — |
| 6-0 | 2.8 | 3.9 | .44 | .70 | .60 | .70 | .70 | .70 | .70 | .24 | — | — | — | .60 | 1.0<br>1.3 | — | 40<br>38 |
| 5-0 | 3.9 | 5.9 | .88 | 1.3 | 1.7 | 1.7 | 1.7 | 1.2 | 1.4 | .51 | 1.2 | .8 | — | 1.2 | 2.9 | 2.1 | 35 |
| 4-0 | 5.9 | 7.8 | 1.3 | 2.1 | 2.8 | 2.9 | 2.9 | 2.3 | 2.3 | 1.0 | 2.1 | 1.4 | — | 1.8 | 3.7<br>5.2 | 3.2<br>4.1 | 34<br>32 |
| 3-0 | 7.9 | 9.8 | 2.1 | 3.1 | 4.0 | 4.1 | 4.3 | 3.5 | 3.8 | 1.5 | 3.1 | 2.2 | 3.2 | 3.0 | 7.9 | 6.2 | 30 |
| 2-0 | 11.8 | 13.3 | 3.2 | 5.0 | 6.5 | 6.0 | 6.5 | 4.8 | 5.7 | 2.3 | 4.0 | 3.1 | 4.0 | 4.0 | 13.1 | 10.7 | 28 |
| 0 | 13.8 | 15.7 | 4.8 | 6.8 | 8.7 | 9.2 | 8.2 | 7.0 | 7.8 | 3.2 | 6.3 | — | 6.0 | 7.5 | 20.8† | 15.7† | 26 |
| 1 | 15.7 | 19.6 | 6.0 | 8.8 | 11.5 | 11.7 | 11.2 | 10.0 | 11.0 | 4.0 | 7.5 | — | — | 10.5 | 28.4† | 25.0† | 25 |
| 2 | 19.7 | 23.6 | 7.8 | 10.7 | 14.5 | 14.4 | 13.8 | 12.0 | 13.5 | 5.6 | — | — | — | 13.0 | 35.9† | — | 24 |
| 3 | 23.6 | 27.5 | 10.8 | 13.2 | — | — | — | — | — | 8.1 | — | — | — | 20.0 | — | — | 23 |
| 4 | 23.6 | 27.5 | 10.8 | 15.2 | — | — | — | — | — | 8.1 | — | — | — | 20.0 | 52† | — | 22 |
| 5 | 27.6 | 31.5 | 13.6 | 18.9 | 27.2 | — | — | — | — | — | — | — | — | 25.1 | 75† | — | 20 |
| 6 | 31.5 | 35.4 | 16.1 | — | — | — | — | — | — | — | — | — | — | 30.0 | 95† | — | 19 |
| 7 | 35.4 | 39.3 | 19.9 | — | — | — | — | — | — | — | — | — | — | 35.1 | 120† | — | 18 |

Note USP XX strength requirements compared with mean averages for ETHICON* sterile sutures

*Trademark of ETHICON INC.

†Straight Pull Tensile Strength as required by USP XX

| USP SIZE | ABSORBABLE | | | | SYNTHETIC ABSORBABLE | | | |
|---|---|---|---|---|---|---|---|---|
| | USP REQUIRED | | | | ETHICON REQUIRED | | | |
| | DIAMETER (MIL.) | | KNOT PULL LBS. | GUT | DIAMETER (MIL ) | | KNOT PULL LBS | ACTUAL VICRYL* KNOT |
| | MIN. | MAX. | | | MIN | MAX | | |
| 11-0 | — | — | — | — | — | — | — | — |
| 10-0 | — | — | — | — | .8 | 1.1 | 24gr | 45gr |
| 9-0 | 1.2 | 1.5 | .05 | — | 1.2 | 1.5 | 45gr | 97gr |
| 8-0 | 2.0 | 2.7 | .10 | — | 1.75 | 2.25 | 60gr | 114.7gr |
| 7-0 | 2.8 | 3.9 | .15 | .30 | 2.50 | 3.10 | .25 | .40 |
| 6-0 | 3.9 | 5.9 | .40 | .50 | 3.50 | 4.20 | .55 | .90 |
| 5-0 | 5.9 | 7.8 | .85 | 1.3 | 5.50 | 6.50 | 1.5 | 2.0 |
| 4-0 | 7.9 | 9.8 | 1.7 | 2.4 | 7.50 | 8.50 | 2.4 | 3.2 |
| 3-0 | 11.8 | 13.3 | 2.7 | 3.9 | 9.50 | 10.50 | 3.9 | 5.0 |
| 2-0 | 13.8 | 15.7 | 4.4 | 5.7 | 12.50 | 13.50 | 6.2 | 7.9 |
| 0 | 15.7 | 19.6 | 6.1 | 8.4 | 15.40 | 16.60 | 8.8 | 10.8 |
| 1 | 19.7 | 23.6 | 8.4 | 11.1 | 18.40 | 19.60 | 11.6 | 14.8 |
| 2 | 23.6 | 27.5 | 9.9 | 14.4 | 21.30 | 22.70 | 14.4 | 19.8 |
| 3 | 27.6 | 31.5 | 13.0 | 17.8 | — | — | — | — |
| 4 | 31.5 | 35.4 | 15.4 | — | — | — | — | — |
| 5 | — | — | — | — | — | — | — | — |
| 6 | — | — | — | — | — | — | — | — |
| 7 | — | — | — | — | — | — | — | — |

Note USP XX strength requirements compared with mean averages for ETHICON sterile sutures
*Trademark of ETHICON, INC.

## Metric Measures

| SUTURE DIAMETER EQUIVALENTS | | | LINEAR MEASURES |
|---|---|---|---|
| NATURAL COLLAGEN | SYNTHETIC ABSORB-ABLES | NONAB-SORBABLE MATERIALS | 1 INCH EQUALS 2.54 CENTIMETERS APPROXIMATE SUTURE LENGTH EQUIVALENTS |
| — | — | — | 5″ ~ 13 cm |
| 0.2 | 0.2 | 0.2 | 9″ ~ 23 cm |
| 0.3 | 0.3 | 0.3 | 10″ ~ 25 cm |
| 0.5 | 0.4 | 0.4 | 12″ ~ 30 cm |
| 0.7 | 0.5 | 0.5 | 14″ ~ 35 cm |
| 1.0 | 0.7 | 0.7 | 18″ ~ 45 cm |
| 1.5 | 1.0 | 1.0 | 24″ ~ 60 cm |
| 2.0 | 1.5 | 1.5 | 27″ ~ 70 cm |
| 3.0 | 2.0 | 2.0 | 30″ ~ 75 cm |
| 3.5 | 3.0 | 3.0 | 36″ ~ 90 cm |
| 4.0 | 3.5 | 3.5 | 40″ ~ 100 cm |
| 5.0 | 4.0 | 4.0 | 54″ ~ 135 cm |
| 6.0 | 5.0 | 5.0 | 60″ ~ 150 cm |
| 7.0 | 6.0 | 6.0 | |
| 8.0 | 6.0 | 6.0 | |
| — | 7.0 | 7.0 | |
| — | — | 8.0 | |
| — | — | — | |

SECTION XIII

# Complete Product Information

## Fast Absorbing Surgical Gut
(PLAIN)
Absorbable Surgical Suture

### DESCRIPTION
Fast Absorbing Surgical Gut suture is a strand of collagenous material prepared from the submucosal layers of the small intestine of healthy sheep, or from the serosal layers of the small intestine of healthy cattle.

Fast Absorbing Surgical Gut sutures are sterile and elicit only a slight to minimal tissue reaction during absorption.

Fast Absorbing Surgical Gut sutures differ from U.S.P. minimum strength requirements by less than 30%.

### ACTIONS
Two important characteristics describe the *in vivo* performance of absorbable sutures; first, tensile strength retention, and second, the absorption rate (loss of mass).

The results of implantation studies of Fast Absorbing Surgical Gut sutures in the skin of animals indicate that nearly all of its original strength is lost within approximately seven (7) days of implantation.

Data obtained from implantation studies in rats show that the absorption of these sutures is essentially complete by the twenty-first (21st) to forty-second (42nd) post-implantation day.

### INDICATIONS
Fast Absorbing Surgical Gut sutures are intended for dermal (skin) suturing *only*. They should be utilized only for external knot tying procedures.

### CONTRAINDICATIONS
These sutures, being absorbable, should not be used where prolonged approximation of tissues under stress is required. These sutures have been designed to absorb at a rapid rate and must be used on dermal tissue only. These sutures should *never* be used on internal tissues.

### WARNINGS
Fast Absorbing Surgical Gut sutures are for dermal use only.

Fast Absorbing Surgical Gut sutures differ from U.S.P. minimum strength requirements by less than 30%.

Do not resterilize.

*Trademark

### PRECAUTIONS
As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

Acceptable surgical practice must be followed with respect to drainage and closure of infected wounds.

### DOSAGE AND ADMINISTRATION
Use as required per surgical procedure.

### HOW SUPPLIED
Fast Absorbing Surgical Gut sutures are available in size 5-0 (metric size 1.5) and 6-0 (metric size 1.0). Revised 1/84

## PDS*
(POLYDIOXANONE)
Dyed and Clear Monofilament Suture
Synthetic Absorbable Suture

### DESCRIPTION
PDS (polydioxanone) monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_X$.

PDS sutures are sterile, nonantigenic, nonpyrogenic, and elicit only a slight tissue reaction during absorption.

PDS sutures differ from U.S.P. maximum diameter requirements by less than 0.08 mm.

### ACTIONS
Two important characteristics describe the *in vivo* performance of absorbable sutures: first, tensile strength retention, and second, the absorption rate (loss of mass). PDS synthetic absorbable suture has been formulated to minimize the variability of these characteristics and to provide wound support through an extended healing period.

The results of implantation studies of PDS monofilament suture in animals indicate that approximately 70% of its original strength remains two weeks after implantation. At four weeks post-implantation, approximately 50% of its original strength is retained, and at six weeks, approximately 25% of the original strength is retained.

Data obtained from implantation studies in rats show that the absorption of these sutures is minimal until about the 90th post-implantation day. Absorption is essentially complete within six months.

### INDICATIONS
PDS monofilament synthetic absorbable sutures are intended for use as absorbable sutures and ligatures. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

### CONTRAINDICATIONS
These sutures, being absorbable, should not be used where prolonged approximation of tissues under stress is required.

### WARNINGS
The safety and effectiveness of PDS (polydioxanone) sutures in neural tissue and in cardiovascular tissue have not been established.

Under certain circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Do not resterilize.

### PRECAUTIONS
The PDS suture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the operator.

As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.

Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption.

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

### ADVERSE REACTIONS
Due to prolonged suture absorption, some irritation and bleeding has been observed in the conjunctiva and mild irritation has been observed in the vaginal mucosa.

### DOSAGE AND ADMINISTRATION
Use as required per surgical procedure.

### HOW SUPPLIED
PDS sutures are available as sterile, monofilament dyed (violet) strands in sizes 9-0 thru 2 (metric size 0.3–5) and in sizes 9-0 and 10-0 (metric size 0.3, 0.2) sterile, monofilament dyed (blue) strands in a variety of lengths, with a variety of needles.

PDS dyed monofilament sutures, sizes 4-0 thru 1 (metric size 1.5–4), are also available attached to CONTROL RELEASE* removable needles.

PDS clear suture strands are available in sizes 7-0 thru 1 (metric size 0.5–4), in a variety of lengths with permanently attached needles. Revised 3/84

# VICRYL*
(Polyglactin 910) Suture
Synthetic Absorbable Suture

# Coated VICRYL*
(Polyglactin 910) Suture
Coated with Polyglactin 370 and
Calcium Stearate
Synthetic Absorbable Suture

## DESCRIPTION
VICRYL (polyglactin 910) synthetic absorbable suture is prepared from a copolymer of glycolide and lactide. These substances are derived respectively from glycolic and lactic acids. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$.

Coated VICRYL synthetic absorbable suture is prepared by coating the VICRYL (polyglactin 910) suture material with a mixture composed of equal parts of a copolymer of glycolide and lactide (polyglactin 370) and calcium stearate.

These sutures are sterile, inert, non-antigenic, nonpyrogenic, and elicit only a mild tissue reaction during absorption. The braided and monofilament sutures are colored violet to enhance visibility in tissue. The braided suture is also available undyed (natural).

VICRYL and Coated VICRYL sutures differ from U.S.P. maximum diameter requirements by less than 0.05 mm.

## ACTIONS
Two important characteristics describe the *in vivo* behavior of absorbable sutures: first, tensile strength retention, and second, the absorption rate (loss of mass).

Subcutaneous tissue implantation studies of both VICRYL and Coated VICRYL suture in rats show at two weeks post-implantation approximately 55% of its original tensile strength remains, while at three weeks approximately 20% of its original strength is retained.

Intramuscular implantation studies in rats show that the absorption of these sutures is minimal until about the 40th post-implantation day. Absorption is essentially complete between the 60th and 90th days.

## INDICATIONS
VICRYL and Coated VICRYL synthetic absorbable sutures are intended for use as absorbable sutures or ligatures.

## CONTRAINDICATIONS
These sutures, being absorbable, should not be used where extended approximation of tissues under stress is required.

## WARNINGS
The safety and effectiveness of VICRYL (polyglactin 910) and Coated VICRYL sutures in neural tissue and in cardiovascular tissue have not been established.

Under certain circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Do not resterilize.

## PRECAUTIONS
As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

The VICRYL suture knots must be properly placed to be secure. Place the first throw in precise position for the final knot, using a double loop; tie the second throw square, using horizontal tension; additional throws are advisable.

Coated VICRYL sutures, which are treated to enhance handling characteristics, require the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the surgeon.

Skin and conjunctival sutures remaining in place longer than 7 days may cause localized irritation and should be removed as indicated.

Acceptable surgical practice must be followed with respect to drainage and closure of infected wounds.

At the discretion of the surgeon, appropriate nonabsorbable sutures may be used to provide additional wound support when VICRYL or Coated VICRYL sutures are used in ophthalmic procedures.

## ADVERSE REACTIONS
Reactions reported in clinical trials which may have been suture related have been minimal. These include skin redness and induration, rare instances of hemorrhage, anastomotic leakage, wound separation in the eye, and abscesses.

## DOSAGE AND ADMINISTRATION
Use as required per surgical procedure.

## HOW SUPPLIED
VICRYL sutures are available sterile, as braided dyed (violet) strands in sizes 9-0 thru 3 (metric size 0.3–6) and undyed (natural) strands in sizes 8-0 thru 3 (metric size 0.4–6), in a variety of lengths, with or without needles, and on LIGAPAK* ligating reels. VICRYL sutures, monofilament, dyed (violet) are available in sizes 10-0 (metric size 0.2) and 9-0 (metric size 0.3), in a variety of lengths with needles.

Coated VICRYL sutures are available sterile, as braided dyed (violet) and undyed (natural) strands in sizes 8-0 thru 3 (metric size 0.4–6), in a variety of lengths, with or without needles, and on LIGAPAK ligating reels. Coated VICRYL sutures are also available in size 8-0 with attached beads for use in ophthalmic surgical procedures.

Both VICRYL and Coated VICRYL sutures are also available in sizes 4-0 thru 1 (metric size 1.5–4) attached to CONTROL RELEASE* removable needles.

Revised: 2/84

*Trademark

# ETHIBOND*
POLYESTER SUTURE
Nonabsorbable Surgical Suture, U.S.P.

## DESCRIPTION
ETHIBOND suture is nonabsorbable, braided, polyester (polyethylene terephthalate or MERSILENE* polyester) fiber uniformly coated with polybutilate, or poly [oxy-1,4-butanediyloxy (1,6-dioxo-1,6-hexanediyl).]. The highly adherent coating is a biologically inert nonabsorbable compound which acts as a lubricant to mechanically improve the physical properties of the uncoated suture by improving ease of passage through tissues and by providing overall improved handling qualities as contrasted to the braided, uncoated fiber.

ETHIBOND sutures are sterile, inert, and elicit minimal tissue reaction. Two-year carcinogenicity studies in Long-Evans rats demonstrated no carcinogenic potential. They are braided for optimal handling properties, and for good visibility in the surgical field, the dyed sutures are colored with D&C Green No. 6.

## ACTIONS
ETHIBOND sutures are strong and nonabsorbable. Subcutaneous tissue implantation in rats shows that no significant change in the retention of tensile strength of the suture occurs during the entire evaluation period of 180 days. Both the polyester fiber suture material and the polybutilate coating are pharmacologically inactive.

## INDICATIONS
ETHIBOND suture is intended for use as a nonabsorbable suture.

## CONTRAINDICATIONS
None.

## WARNINGS
ETHIBOND polyester sutures have not been evaluated in ophthalmic surgery.

Do not resterilize.

**PRECAUTIONS**
As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

As with all sutures, acceptable surgical practice must be followed with respect to drainage and closure of infected wounds.

Knot security requires the standard surgical technique of flat and square ties, with additional throws if indicated by surgical circumstances and the experience of the operator.

**ADVERSE REACTIONS**
Slight erythema and/or induration at suture sites have been reported in approximately 2% of the patients in whom ETHIBOND sutures have been used, a not unexpected reaction.

**DOSAGE AND ADMINISTRATION**
Use as required per surgical procedure.

**HOW SUPPLIED**
ETHIBOND polyester sutures are available as sterile, braided, green and undyed (white) strands in U.S.P. sizes 7-0 thru 5 (metric size 0.5–7) in a variety of lengths, with and without permanently attached needles.

ETHIBOND polyester sutures, green braided, in U.S.P. sizes 4-0 thru 1 (metric size 1.5–4) are also available attached to CONTROL RELEASE* removable needles.

ETHIBOND sutures, green and undyed, are also available attached to Teflon† felt pledgets measuring 1/8″ × 1/8″ × 1/16″ (3.0mm × 3.0mm × 1.5mm), 1/8″ × 1/4″ × 1/16″ (3.0mm × 7.0mm × 1.5mm), or 3/8″ × 3/16″ × 1/16″ (9.0mm × 4.0mm × 1.5mm). Revised 4/84

## PROLENE*
### POLYPROPYLENE SUTURE
Nonabsorbable Surgical Suture, U.S.P.

**DESCRIPTION**
PROLENE Polypropylene Suture, U.S.P. (clear or pigmented) is an isotactic crystalline stereoisomer of a linear hydrocarbon polymer containing little or no unsaturation. The pigmented suture contains Copper Phthalocyanine Blue.

**ACTIONS**
PROLENE Polypropylene Suture, U.S.P. causes a minimal, transient acute inflammatory reaction. This is followed by the formation of a microscopic layer of fibrous tissue around the suture. The suture is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

**INDICATIONS**
PROLENE Polypropylene Suture, U.S.P. may be used wherever Nonabsorbable Surgical Suture, U.S.P. is recommended. Due to its relative biological inertness, it is recommended for use where the least possible suture reaction is desired. As a true monofilament, PROLENE Polypropylene Suture, U.S.P. resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion.

Because of its lack of adherence to tissue, PROLENE Polypropylene Suture, U.S.P. is efficacious as a pull-out suture.

**CONTRAINDICATIONS**
There are no known contraindications.

**WARNINGS**
Do not resterilize.

**PRECAUTIONS**
As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needleholders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the operator.

**ADVERSE REACTIONS**
Transitory local inflammatory reaction have been reported.

**DOSAGE AND ADMINISTRATION**
Use as required per surgical procedure.

**HOW SUPPLIED**
PROLENE* Polypropylene Sutures, pigmented, are available as sterile strands in U.S.P. sizes 11-0 thru 2 (metric size 0.1–5) in a variety of lengths, with and without permanently attached needles. PROLENE Polypropylene Sutures, clear, are available as sterile strands in U.S.P. sizes 7-0 thru 2 (metric size 0.5–5) in a variety of lengths, with and without permanently attached needles.

PROLENE Polypropylene Sutures, pigmented and clear, in U.S.P. sizes 4-0 thru 2 (metric size 1.5–5) are also available attached to CONTROL RELEASE* removable needles.

PROLENE Polypropylene Sutures sizes 0 thru 5-0 are also available attached to Teflon† or Dacron† felt pledgets measuring 1/8″ × 1/8″ × 1/16″ (3.0mm × 3.0mm × 1.5mm), 1/8″ × 1/4″ × 1/16″ (3.0mm × 7.0mm × 1.5mm), or 3/8″ × 3/16″ × 1/16″ (9.0mm × 4.0mm × 1.5mm). An additional size for the Dacron Pledget is also available measuring 1/16″ × 1/4″ × 1/4″ (1.5mm × 6.0mm × 6.0mm). Revised 9/82

## ETHI-PACK* Surgical Steel

TO PREVENT STEEL SUTURE FROM KINKING WE SUGGEST THESE PROCEDURES FOR STEAM STERILIZING AND HANDLING . . .

1. Wrap tube of ETHI-PACK surgical steel in muslin or paper wrapper or in a plastic peel-apart envelope. DO NOT BEND TUBE . . . KEEP IT STRAIGHT AT ALL TIMES.

2. For flash sterilization, place unwrapped tube of ETHI-PACK steel in autoclave tray. Sterile tube is transferred to instrument table, using aseptic technique, immediately after autoclaving.

3. Vented caps should not be removed during autoclaving. The vented caps permit steam entry, circulation and exit.

4. Autoclave by standard recommended cycle for wrapped or unwrapped items. CAUTION: Since caps are vented, UNWRAPPED TUBES CANNOT BE STORED STERILE. Wrapped tubes may be kept in sterile storage after autoclaving.

5. During use, remove yellow cap from either end of tube. LEAVE STRANDS IN TUBE TO PREVENT KINKING . . . simply withdraw a strand as needed.

6. Before replacing yellow cap after use, clean strands and tube of any blood or organic debris. Unused strands may be re-autoclaved repeatedly in the tube.

ETHICON* packaging of Surgical Steel sutures eliminates kinking and bending of strands. Specially prepared ETHICON monofilament steel is free of barbs . . . multifilament steel does not broom.

Revised 5/82

## ETHICON* Bone Wax

**DESCRIPTION**
ETHICON Bone Wax is a sterile mixture of beeswax and isopropyl palmitate, a wax-softening agent. It is opaque and has a waxy odor.

*Trademark
†TM E.I. Dupont de Nemours & Co. for TFE Fluorocarbon.

**ACTIONS**
ETHICON Bone Wax achieves local hemostasis of bone by acting as a mechanical (tamponade) barrier. It does not act biochemically and is minimally resorbable.

**INDICATIONS**
ETHICON Bone Wax may be used for the control of bleeding from bone surfaces.

**CONTRAINDICATIONS**
Bone Wax should not be used where rapid osseous regeneration and fusion are desired.

**WARNINGS**
ETHICON Bone Wax should not be resterilized or subjected to excessive heat. Bone Wax may inhibit osteogenesis and may act as a physical barrier to the reparative process.

**PRECAUTIONS**
Bone Wax should be used sparingly. Excess Bone Wax should be removed from the operative site. The package should be opened just prior to use to minimize the possibility of contamination and excessive drying.

**ADVERSE REACTION**
Mild inflammatory reactions have been reported in tissues immediately adjacent to the site of implantation. Studies have suggested that Bone Wax as a foreign body may impair the ability of the cancelous bone to clear bacteria. In animal models, the local accumulation of foreign body giant cells has been observed and histologic examination has revealed the appearance of macrophages and occasionally polymorphonuclear leukocytes and lymphocytes.

**DOSAGE ADMINISTRATION**
Bone Wax should be used immediately after removal from the package. Using aseptic technique, Bone Wax should be warmed to the desired consistency by manipulation with the fingers or by immersion of the unopened foil packet in a warm sterile solution.

**HOW SUPPLIED**
ETHICON Bone Wax is available sterile in individual foil envelopes, each containing 2.5 grams, and packaged in an individually sealed overwrap packet.

December 1981

*Trademark

ETHICON, INC.
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Somerville, New Jersey 08876-0151

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